"A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients"

Dissertation

Submitted to the Faculty of Nursing

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

In partial fulfilment of the requirement for the degree of

M. Sc. in Medical Surgical Nursing (Cardiological/ Cardiothoracic Vascular Nursing)

By

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JULY 2024

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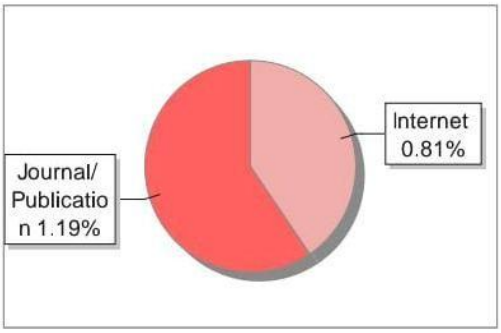

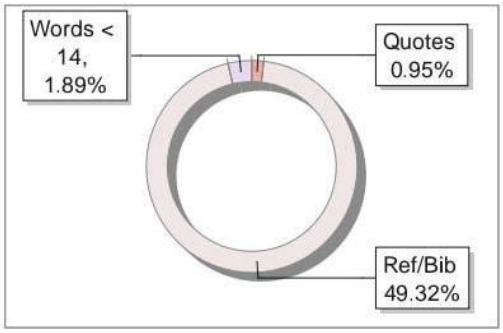

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IHEC-SR LETTER OF PERMISSION

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Institutional Human Ethics Committee- Student Research (IHEC-SR)

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Ref Number: AIIMS/BPL/IHECSR/July/22/MscN/09 **Date:** 28th February 2023

Letter of Permission

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 7th meeting held on 22nd February 2023 discussed your proposal titled **"A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of Blood Pressure among Hypertensive patients"** and evaluated it for suitability for your dissertation as required for fulfilment of MSc (Nursing).

Following members attended the meeting:

1. Prof. D. K. Pal, Former HoD Community Medicine, GMC, Bhopal……Chairperson
2. Prof. Rajnish Joshi, Professor of General Medicine, AIIMS, Bhopal……Member
3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal……Member
4. Dr. Sunita Athawale, Professor of Anatomy, AIIMS, Bhopal……Member
5. Dr. Girish Bhatt, Addl. Professor of Pacdiatrics, AIIMS, Bhopal……Member
6. Dr. Ujjawal Khurana, Assoc. Professor of Pathology, AIIMS, Bhopal……Member
7. Dr. Ankur Joshi, Assoc. Professor of CFM, AIIMS, Bhopal……Member
8. Mr. Trivesh Goswami, Law Officer, AIIMS Bhopal,……Member
9. Dr. Shashank Purwar, Professor of Microbiology, AIIMS, Bhopal……Member Secretary

The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

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ABSTRACT

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Introduction

Hypertension is known as the silent killer because of its uncertain symptom. Therefore, early detection efforts are needed such as regular blood pressure check and effective management. Both Pharmacological and Non-pharmacological management strategies for hypertension. This study aimed to determine the effectiveness of one of the non-pharmacological management : " warm water foot soak therapy" in reduction of blood pressure among hypertensive patients.

Methodology

Experimental study design - Randomized Controlled Trial was conducted among 60 participants among hypertensive patients using convenient sampling technique. Participants were randomly and equally allocated into Experimental and Control group with the help of computer generated randomization list. Sequentially Numbered Opaque Sealed Envelope (SNOSE) were used for allocation concealment. Experimental group received "Warm foot soak therapy" of both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 consecutive days. Before and after intervention blood pressure assessment were taken in both groups. Data were analyzed using SPSS ver. 27

Result

Homogeneity of socio-demographic, clinical and pre-intervention blood pressure among both groups were statistically established using chi-square test ($p > 0.05$). Paired t test concluded that,

warm foot soak therapy were having statistically significant effect on blood pressure ($p < 0.05$) and there was a significant reduction in blood pressure among hypertensive patients ($p=0.01$). The study also discovered that there is no significant association between selected demographics & clinical variables with pre-interventional change in blood pressure except for the dietary pattern (Veg) in both control and experimental group & presence of comorbidity (DM) in experimental group among hypertensive patients at level of significance 0.05

Conclusion

The study demonstrated that warm foot soak therapy have an effect on reduction of blood pressure among hypertensive patients.

Keywords: Hypertension, Warm foot soak therapy, Reduction of blood pressure, hypertensive patients, non- pharmacological management

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LIST OF ABBREVIATIONS

SL NO.	ABBREVIATIONS	EXPANSION
1.	BMI	Body Mass Index
2.	Cm	Centimeter
3.	df	Degree Of Freedom
4.	HTN	Hypertension
5.	AHA	American Heart Association
6.	FET	Fisher Exact Test
7.	I-CVI	Item-Content Validity Index
8.	S-CVI	Scale- Content Validity Index
9.	IHEC-SR	Institutional Human Ethical Committee- Student Research
10.	UPHC	Urban Primary Health Center
11.	SBP	Systolic Blood Pressure
12.	DBP	Diastolic Blood Pressure
13.	LOP	Letter Of Permission
14.	NS	Not Significant
15.	S	Significant
16.	SNOSE	Sequentially Numbered Opaque Sealed Envelop

LIST OF SYMBOLS

SL NO.	SYMBOLS	EXPANSION
1.	$\chi 2$	Chi square
2.	n	Sample size
3.	p	Level of Significance
4.	t	t-test
5.	r	Correlation coefficient
6.	*	Chi square
7.	**	Fischer exact test
8.	f	Frequency
9.	λ	variance
10.	^{0}C	Degree Celsius

CHAPTER I

INTRODUCTION

CHAPTER I

INTRODUCTION

“ High blood pressure is a silent killer. It can strike without warning, but with proper care and lifestyle changes, it can be controlled.”

- Andrew Hall

Background of the study

“ The silent killer " refers to hypertension, an asymptomatic condition marked by increased systolic and diastolic blood pressure (Potter & Perry, 2005).[1] It is the biggest single cause of an increase in mortality and worldwide disease burden. (2015) Poulter, Prabhakaran, and Caulfield. [2] The reason why elderly people experience hypertension more frequently is because the blood vessels shape and function have changed.[3] They also have a higher risk of stroke, chronic kidney failure, congestive heart failure, dementia, congestive bleeding, and coronary artery disease. According to the global burden of hypertension, 1.56 billion persons were predicted to have high blood pressure by 2025, up from the expected one billion in 2017. Now One of the most common chronic diseases in India is hypertension.

Age, gender, marital status, employment, alcohol consumption, excessive salt intake, and smoking history are just a few of the risk factors that have been connected to hypertension. Hypertension can be managed and controlled with the appropriate care, despite the fact that there is no ideal medication for it. The mortality and morbidity linked to hypertension can be decreased by effective treatment adherence combined with blood pressure-influencing factors. Generally speaking, managing hypertension can be done with or without the use of pharmaceuticals. Although taking drugs can provide temporary alleviation from problems, pharmacological therapy makes use of a variety of drug classes. Non-pharmacological management techniques include herbal therapy, nutritional therapy, progressive relaxation, breathing exercises, music therapy, acupuncture, reflexology, aromatherapy, and hydrotherapy which is spreading quickly both among rural and urban populations.[4]

Although a multitude of medications and treatment methods exist for hypertension, none ensure complete recovery. The two main goals of hypertension therapy are to maintain blood pressure (BP) within the normal range and to enhance the health and quality of life of older adults.5

In general, there are two approaches to managing hypertension: pharmacological and non-pharmacological. According to the 2017 AHA/ACC recommendation, patients with stage 1 hypertension who do not have these symptoms should have their 10-year risk of cardiovascular disease calculated. It makes sense to conduct lifestyle modification alone for three to six months if the risk is less than 10%. It is advised to change one's lifestyle and take medicine for stage 2 hypertension in patients with pre-existing conditions such as diabetes mellitus, chronic kidney disease, and a 10-year risk of cardiovascular events of 10% or higher. Pharmacological management makes use of medications such as beta blockers, calcium channel blockers, vasodilators, and diuretics in relation to the degree of adherence and mechanism of action of the medicine. The side effects of this pharmaceutical treatment differ according on how long and how intense it is. Drug administration-related adverse effects, geriatric disobedience in taking anti-hypertensive medications, and dependency effects are just a few of the issues with pharmacological therapy for the aged (Aronow & Banach, 2012).[6] In order to support pharmacological treatment, non pharmacological management might be used (Muttaqin, 2009). [7]

Lifestyle changes such as giving up smoking, cutting back on excessive alcohol intake consuming less salt and fat, eating more fruits and vegetables, losing weight, exercising, and receiving complementary therapy are examples of non-pharmacological management. Individual lifestyle factors each have a partially additive influence on blood pressure reduction, which increases the effectiveness of pharmaceutical treatment.There are various forms of hydrotherapy, including sitzbaths, water massages, compressing, wrapping with a damp towel, and soaking feet. Warm water

is used in non-pharmacological treatment techniques like foot soak therapy to relax blood vessel muscles and improve blood flow.

Heat is known to cause the body to expand blood vessels, lower blood viscosity, relieve tense muscles, speed up tissue metabolism, and widen capillaries. The body needs heat therapy for these reasons.

It is known that stimulating the pituitary gland causes endorphin chemicals to be released, which activate the parasympathetic nervous system and decrease activity instead of the sympathetic nerves. This causes a generalized vasodilation, which lowers blood pressure and decreases peripheral resistance. There are nerve sites on the human foot soles that correspond to different body organs. Warm water between 31 and 37 °C produces vasodilation, which can open blood flow, so there may be a drop in blood pressure following the warm water foot bath.

Significance or Need of the study

One of the most prevalent diseases impacting people on a global scale is hypertension. In order to reduce the prevalence of hypertension in the general population, health care practitioners must not only diagnose and treat individuals with hypertension but also encourage a healthy lifestyle and preventive measures. Non-pharmacological management should begin in the early stages of the illness and should be continued with hypertension medication strategies. Warm water is used in techniques like warm foot soak therapy to relax blood vessels, muscles, and tissue and enhance blood flow. Warm foot soak therapy is considered effective, particularly for the elderly, because it can be used in a more straightforward and affordable way, which enhances its therapeutic effects. Additionally, since water is a readily available source of life, hydrotherapy has the potential to become a mainstay treatment, particularly for lowering blood pressure in the

elderly. Warm water has physiological effects on the body, including lowering edema, relaxing muscles, reducing discomfort, opening up capillaries, and warming the body. The need of this study is to assess the effectiveness of warm foot soak therapy on the reduction of blood pressure among hypertensive patients.

Research problem

A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients.

Research questions

1. Is warm foot soak therapy effective to reduce blood pressure?
2. How much is the change in blood pressure after giving warm foot soak therapy?
3. Which of the sociodemographic variables are associated with pre-interventional blood pressure?
4. Which of the clinical variables are associated with pre-interventional blood pressure?

e. Aims and Objectives

Aim of study

The aim of study is to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients.

Objectives of study

1. To assess the blood pressure among hypertensive patients before the warm foot soak therapy
2. To assess the effectiveness of warm foot soak therapy among hypertensive patients
3. To find association of selected sociodemographic variables with pre interventional change in blood pressure among hypertensive patients
4. To find association of selected clinical variables with pre interventional change in blood pressure among hypertensive patients

Hypotheses

H0 : There will be no significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance

H1 : There will be significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance

H2 :There will be significant association between selected sociodemographic variables with pre interventional change in blood pressure among both groups at 0.05 level of significance

H3 : There will be significant association between selected clinical variables with pre interventional change in blood pressure among both groups at 0.05 level of significance

Operational definition

Effectiveness : The desired result produced by intervention, In this study effect referred to the ability of warm foot soak therapy to bring about a decrease in blood pressure as measured by the investigator using a digital sphygmomanometer

Reduction in blood pressure : Blood pressure is created by the force of blood pushing against

the walls of blood vessels (arteries) as it is pumped by the heart (WHO) [9], In this study reduction referred as the decrease in blood pressure after giving intervention among hypertensive patients

Warm foot soak therapy : It is the local immersion of both feet and ankles in warm water of temperature 37-40 degree Celsius ,In this study warm foot soak therapy referred to the immersing of the both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius (monitor by using a water thermometer) for a period of 15 minutes administered by the investigator.

Hypertensive patients : In this study , the patients having stage 1 and stage 2 hypertension

(Hypertension is diagnosed if ,when it is measured on two different days , the systolic blood pressure on both days is >/= 140 mmHg and/or the diastolic blood pressure reading on both days is >/= 90 mmHg : WHO) [8]

According to AHA blood pressure stages[9], adult patients who attending the NCD clinics of UPHC Berkheda Patani & Sai Baba and fulfills the inclusion criteria

Blood Pressure Categories

American Heart Association.

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 – 139	or	80 – 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

Figure No. 1 : AHA Blood Pressure Categories

Delimitation

This study delimited to :

a) The adult patients attending the NCD clinics of UPHC – Berkhada Patani & Sai Baba Nagar during the period of data collection

b) Study is only delimited to patients having hypertension according to inclusion criteria

Conceptual framework

A conceptual framework is a set of logically related concepts used to explain the relationships between variables in a study. A conceptual framework is typically created by a researcher based on their own experience, previous study results or the concepts used in different theories & studies.

The present study is intended to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients.

The theoretical framework adopted by the researcher for the present study is based on Wiedenbach's helping art of clinical nursing theory (1969).[11]

Nursing, according to Wiedenbach, is the "practice of determining the patient's need through careful observation and examination of patients' behavioral and physical signs, determining the cause of symptoms, and determining if the patient requires assistance from a nurse." Wiedenbach defined her theory as follows:

a. Philosophy:

The attitude and belief of the nurse about life and how it affects the reality.

b. Purpose

Purpose is the accomplishment of the nurse that she gets after the action done for the patient.

c. Practice

Practice is defined as the nurse's observable action needed to fulfill the need of the patient.

d. Art

Nursing is the art of determining the patient's need, setting goals and actions that will help the patient, and guiding those actions into a medical strategy that improves the patient's quality of life. She proposed a prescriptive model based on three components: the central purpose, the prescription, and the reality.

In this model, the nurse creates a prescription based on the central purpose and applies it based on the reality of the situation.

The conceptualization of nursing practice in this study is based on 4 main steps.

Step 1: Identifying the need of help

Step 2: Ministering the need of help

Step 3: Validating the need for help met or not

Step 4: Coordination

Step 1: Identifying the need of help

The nurse identifies the need for reducing blood pressure among hypertensive patients by assessment of sociodemographic (Age, Gender, Occupation, Dietary pattern, Smoking habit, History of Alcoholism and BMI) and clinical variables (Duration of hypertension, no.of anti-hypertensive drugs and presence, type of comorbidity). The effectiveness of intervention will be determined by assessing blood pressure before and after the intervention.

Step 2: Ministering the need of help

It is the fulfillment of the identified need by provision of appropriate interventions.

It has 2 components;

- ❖ Prescription
- ❖ Reality

Prescription

It is the plan of action needed for the patient. In present study, the prescribed interventions is warm foot soak therapy to decrease the blood pressure among hypertensive patients.

Reality

It includes the factors influencing prescribed interventions in a particular situation.

The components include;

a. Agent: Investigator

b. Recipient: Hypertensive patients

c. Goal: Reduction in blood pressure

d. Means and activities:

Group 1: Will be receiving warm foot soak therapy,it is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 consecutive days. Each day pre-interventional and post-interventional blood pressure will be taken.

Group 2: Will not be getting any intervention and e ach day pre-interventional and post-interventional blood pressure will be taken.

Framework: UPHC of Berkheda Patani & Sai Baba Nagar

Step 3: **Validating the need for help met or not**

It refers to checking whether the need of the patient was met through the planned interventions. In this study, blood pressure will be taken before and after the intervention. Observations will be taking during 3-day intervention schedule.

Step 4: Coordination

It includes reporting, consulting and conferring of the outcome. In this study the outcomes will be communicated to the client and family members

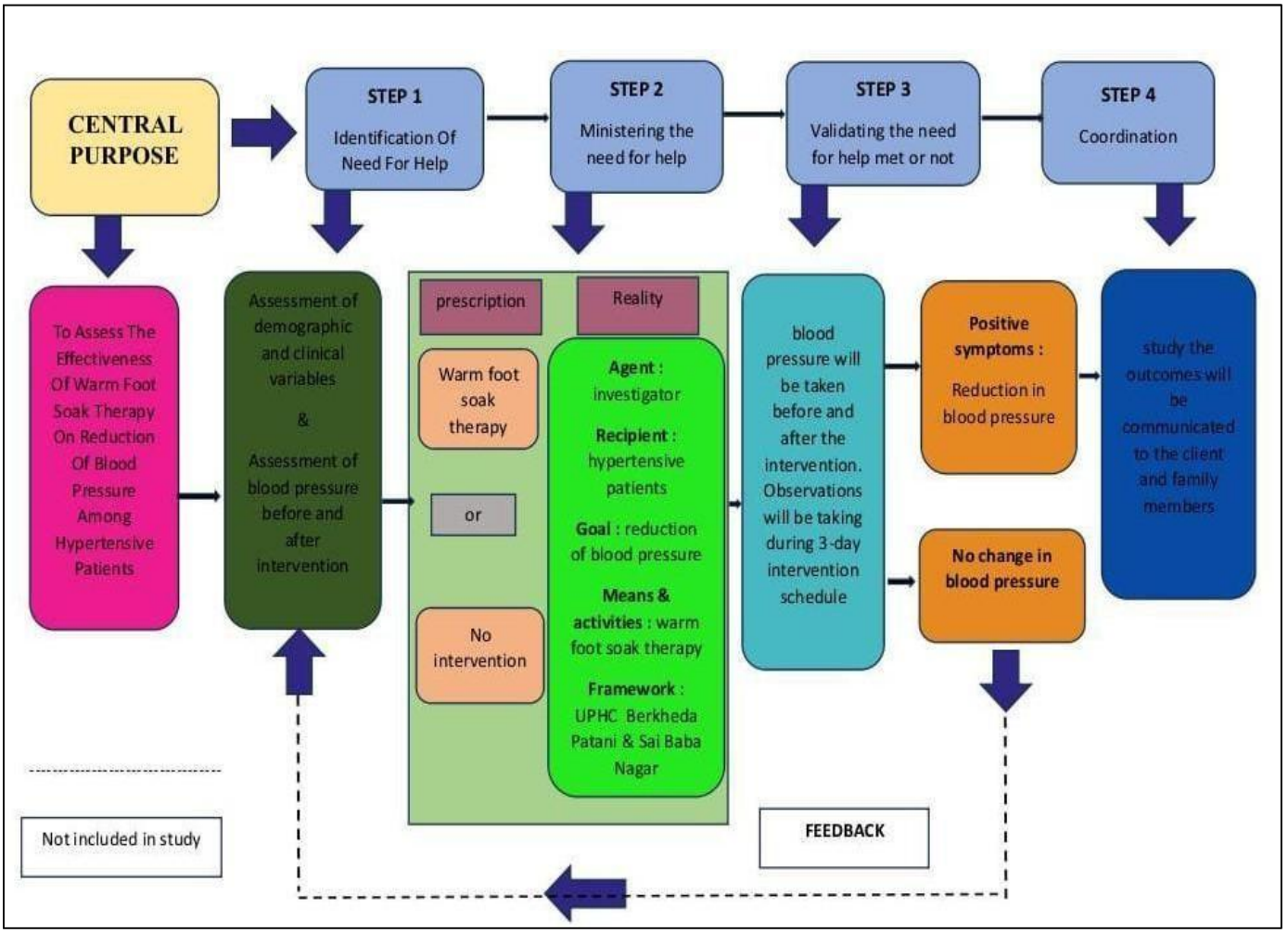
CENTRAL PURPOSE
STEP 1
Identification Of Need For Help
STEP 2
Ministering the need for help
STEP 3
Validating the need for help met or not
STEP 4
Coordination
To Assess The Effectiveness Of Warm Foot Soak Therapy On Reduction Of Blood Pressure Among Hypertensive Patients
Assessment of demographic and clinical variables
&
Assessment of blood pressure before and after intervention
prescription
Reality
Warm foot soak therapy
or
No intervention
Agent : investigator
Recipient : hypertensive patients
Goal : reduction of blood pressure
Means & activities : warm foot soak therapy
Framework : UPHC Berkheda Patani & Sai Baba Nagar
blood pressure will be taken before and after the intervention. Observations will be taking during 3-day intervention schedule
Positive symptoms :
Reduction in blood pressure
No change in blood pressure
study the outcomes will be communicated to the client and family members
Not included in study
FEEDBACK

Figure No. 2: Conceptual Framework based on Wiedenbach's helping art of clinical nursing theory (1969)

Summary

The "silent killer," hypertension, can happen for a number of causes. In order to manage hypertension, the health care delivery system employs both non-pharmacological and pharmaceutical techniques. We can manage hypertension affordably by using warm foot soak therapy. The goal of this study is to identify the most efficient, economical treatment that can be a part of a hypertension control plan.

CHAPTER - II

REVIEW OF LITERATURE

CHAPTER - II

REVIEW OF LITERATURE

Literature review is one of the most important steps in research process. The main purpose of literature review is to convey the readers what has been already done and the previous knowledge and findings on a particular area of interest. [12]

An extensive literature review has been done in various databases like Pub Med and Google Scholar. Keywords used for literature search were Hypertension, warm foot soak therapy, hydrotherapy, complementary therapy, nursing interventions. Following Literature review includes what has been already done in the area of hypertension.

Literature is arranged in following subheadings;

Section A : Incidence and risk factors related to hypertension

Section B : Non - pharmacological management of hypertension

Section C : Nursing intervention on reduction of hypertension

Section D : Effect of warm foot soak therapy

Section A : Incidence and risk factors related to hypertension

Singh S, Shankar R et al. (2023) cross-sectional study was conducted to evaluate the prevalence of Hypertension and its related factors and to estimate the awareness, treatment and adequacy of Hypertension control among 640 participants aged 25-64 years among urban populations in Varanasi. The result showed that Hypertension prevalence was 32.9 percent (males: 40.9 percent, females: 26.0 percent). Tobacco and alcohol use, overweight, obesity and abdominal obesity were associated with Hypertension. The study concluded that about a third of the participants were hypertensive and about half of the participants were pre- hypertensive in this region. The level of awareness, treatment and control of Hypertension was very low.[12]

Geevar et al (2022) conducted a comparative think about to discover the predominance of hypertension and the levels of mindfulness, treatment and control of hypertension within the youthful grown-ups in Kerala, India compared to more seasoned grown-ups. They included 1,221 young adults (men 36.7%) within the age gather 20–39 a long time from the 5,150 members of the Cardiological Society of India Kerala Coronary supply route infection (CAD) and its Chance variables Predominance (CSI Kerala CRP) Think about. They found out that among the youthful grown-ups, 11.2% had hypertension and 33.3% had pre-hypertension. Hypertension was about three times more predominant among men than ladies (20.5 vs. 7.5% $p < 0.001$) whereas in more seasoned grown-ups there was no contrast between men and ladies in its predominance. Male sex , urban home, stomach obesity and hypercholesterolemia were noteworthy components favoring hypertension within the youthful grown-ups. Mindfulness and treatment of hypertension were altogether destitute among more youthful grown-ups compared to more seasoned grown-ups. The ponder concludes that one eighth of youthful subjects had

hypertension with three times higher predominance of hypertension among men compared to ladies. Mindfulness, treatment and control of hypertension were less among youthful grown-ups and more regrettable in youthful men compared to youthful ladies. Distinguishing hypertension and measures to control it are imperative and ought to be particularly focused on to youthful men.[13]

Mostafa bijani et al (2020) conducted an analytical-cross sectional study, out of 10,111 people included within the think about, 5546 (54.86%) subjects were ladies and 4565 (45.16%) other were men. The generally predominance rate of hypertension was evaluated as 46.6%. In this consider, (16/1%) of the members were with HTN organize 1, and (17/9%) of them were with HTN organize 2. The comes about appear that there were critical positive relationships among HTN and age, BMI, HDL, TG, BUN, High mountain, smoking, physical movement, cardiovascular maladies, diabetes, and renal disappointment . Predominance of HTN in this think about populace is significant. Subsequently, it is proposed that well-being framework ought to program a few plans to anticipate hypertension's predominance and kill its hazard components**.** [14]

Mirzaei et al (2020) conducted a consider among grown-up Iranian populace to assess the mindfulness, treatment, and control of hypertension and related variables. They concluded that hypertension known as the quiet executioner, could be a major hazard figure for cardiovascular disease. Mindfulness and treatment of hypertension isn't fitting within the

world, and this has driven to an increment in mortality and dismalness caused by uncontrolled hypertension.[15]

Ghosh S, Kumar M et al (2019) conducted a cross-sectional study among people matured15–49 in India at the national, state and area level, , to discover out the predominance and related hazard components of hypertension. The consider uncovered that age-adjusted predominance of hypertension in India was 11.3% (95% CI 11.16% to 11.43%) among people matured between 15 and 49 and was four rate focuses higher among guys 13.8% (95% CI 13.46% to 14.19%) than among females 10.9% (95% CI 10.79% to 11.06%). People within the urban area (12.5%, 95% CI 12.25% to 12.80%) had a hardly higher predominance than people in rustic area (10.6%, 95% CI 10.50% to 10.78%). The extent of populace enduring from hypertension changed enormously between states, with a predominance of 8.2% (95% CI 7.58% to 8.85%) in Kerala to 20.3% (95% CI 18.81% to 21.77%) in Sikkim. Progressing age, obesity/overweight, male sex, financial status and utilization of liquor were found to be themajor indicators of hypertension.[16]

Amponsem-Boateng C et al (2019) conducted a cross-sectional study was employed in five different SHSs in the Ashanti region of Ghana from December 2018 to February 2019 with structured questionnaires and physical screening of participants. Logistic regression analysis was performed to test for relation knowledge and risk factors on HTN.The results found that the overall prevalence of pre-HTN within the group was 33.8%, with stages 1 and 2 HTN

prevalence of 5.4%. Sixty-three percent do not have an idea of what HTN is, and positive associations were found between no physical exercises, no addition of extra salt, type of food often eaten and family history. It concludes that prevalence in pre-HTN within students at the SHS level with low knowledge and high risk factors on the disease. This indication is beneficial to target the interventional programs on this population at this early stage by inculcating education on HTN prevalence and its risks in the educational curricular by the government. [17]

Vinita Thapliyal et al (2017) conducted a ponder almost pointed to gage the Prevalence of hypertension and its related chance factors among grown-ups of common Uttrakhand. It may be a cross sectional community based consider. Diagram was conducted in nation zones of Uttrakhand, to make a test degree of 300 grown-ups (18-45yr), utilizing WHO STEPS overview. Midriff Circumference, Blood weight, Body Mass List of the individuals was calculated. Inside the test people based on systolic BP, 61.3% were non-hypertensive, 29.7% were pre-hypertensive and 9% were hypertensive. Based on diastolic BP, 43.3% were non-hypertensive, 32.7% were pre-hypertensive and 24% were hypertensive. Subjects with hypertension and pre-hypertension have higher BMI and midsection circumference. A tall prevalence rate of pre-hypertension and hypertension was portrayed in nation zones of Uttrakhand region.4.8% of the female individuals had systolic tall blood weight compared to

the 11.9% of the male individuals. On the other hand, 21.8% of the female individuals had diastolic tall blood weight compared to the over 25% of the male individuals.[18]

Lacruz et al (2015) conducted an observational think about to assess the predominance and rate of hypertension inside an grown-up population-based cohort. They were included 967 men and 812 ladies matured 45 to 83 a long time. BP was measured agreeing to a standardized convention with oscillometric gadgets and hypertension was characterized as cruel systolic BP (SBP) ≥140 mmHg and/or diastolic BP (DBP) ≥90 mmHg and/or utilize of anti hypertensive medicine on the off chance that hypertension was known and inspected predominance and frequency of hypertension, by age and sex. The age-standardized predominance of hypertension at pattern was 74.3% for men and 70.2% for ladies. Hypertension prevalence and frequency within the CARLA Consider show up to be hoisted compared with other ponders. The diminish of BP over time appears to be caused by made strides hypertension control due to interventional impacts of our observational consider and moved forward well being care**.** [19]

Section B : Non - pharmacological management of hypertension

Pratyusha Kodela et al (2023) conducted a Story Survey on Administration of Hypertension With Non-pharmacological Meditations: This article has compiled ponders like efficient surveys, meta-analyses, and randomized controlled trials and looked into the part of non-pharmacological administration of HTN, counting way of life adjustments like work out, weight misfortune, dietary intercessions like dietary approaches to halt hypertension (Sprint) eat less, moo sodium slim down, constraining liquor utilization, smoking cessation and push administration to assist control blood weight. Be that as it may, non-pharmacological intercessions ought to be started in an early stage, and for proper administration of HTN, we may have to be incorporate both pharmacological and non-pharmacological meditations. Weight misfortune is the foremost advantageous non- pharmacological intervention to oversee HTN, taken after by the DASH slim down, work out, liquor, smoking, and administration of stretch. These ought to be started within the early stage and utilized in conjunction with pharmacological intercession as it were to be profoundly viable.Clinicians play a pivotal part in clarifying the dangers of untreated HTN to patients and emphatically empowering them with respect to long-term adherence to way of life meditations like weight misfortune, work out, bringing down liquor utilization, and smoking cessation. The utilize of portable innovation and individual computerized gadgets can be successful to assist track and keep up sound way of life changes like weight misfortune and work out, particularly when back and responsibility through dynamic intercession are not accessible. [20]

Shao t et al (2023) conducted a think about to compare the potential short-term impacts of non-pharmacological mediations (NPIs) on prehypertensive individuals, and give prove for mediation models with potential in future community-based administration. In this Bayesian arrange meta-analysis, Pub med, Em base, and Web of science were screened up to 16 October 2021. Prehypertensive patients (Systolic blood weight, SBP 120–139 mmHg / Diastolic blood weight, DBP 80–89 mmHg) with a follow-up period longer than 4 weeks were focused on. Sixteen NPIs were distinguished amid the scope audit and categorized into five bunches. Lessening in SBP and DBP was chosen as result factors and the impact sizes were compared utilizing consistency models among intercessions and intercession bunches. Review approach was utilized to survey the certainty of prove. The think about found that thirty-nine ponders with 8279 members were included. For SBP, fortify works out were the foremost invaluable intercession gather when compared with regular care (cruel difference=−6.02 mmHg, 95% CI −8.16 to −3.87), and combination work out, isometric work out, and oxygen consuming work out were the three most viable particular intercessions. For DBP, unwinding was the foremost beneficial intercession gather when compared with normal care (cruel difference=−4.99 mmHg, 95% CI −7.03 to −2.96), and needle therapy, contemplation, and combination work out were the three most compelling particular mediations. No irregularity was found between roundabout and coordinate prove. In any case, heterogeneity was identified in a few thinks about. It concludes that NPIs can bring short-term BP decrease benefits for prehypertensive patients, particularly work out and unwinding. NPIs might possibly be included in community-based malady administration for prehypertensive populace once long-term real-world viability and cost-effectiveness are demonstrated. [21]

Le et al (2022) conducted a ponder to decide the foremost viable non-pharmacological mediations to control the blood weight variety in more seasoned hypertensive patients. Essential endpoints were office systolic blood weight (SBP) and diastolic blood weight (DBP). The quality of prove was surveyed utilizing the "risk of inclination 2″ apparatus and the Evaluating of Proposals Evaluation, Advancement, and Assessment (Review) strategy. They performed a Bayesian organize meta-analysis utilizing R-4.0.2 program to compare the adequacy of mediations. And found that 36 qualified ponders (3,531 patients) with a middle follow-up of 12 weeks, surveying 18 non-pharmacological intercessions, were included. The rates of tall, direct, moo, and exceptionally moo certainty prove were 16.7%, 38.9%, 33.3%, and 11.1%, separately. Ponder concludes that tall certainty prove proposes that self-management instruction is most viable in bringing down SBP and DBP in more seasoned patients with hypertension, taken after by moderate-intensity oxygen consuming work out. Moderate-intensity resistance preparing is the foremost compelling work out for bringing down SBP. [22]

Verma et al (2021) conducted a think about on adequacy of Non-pharmacological administration of hypertension and recognized that way of life adjustments counting changes within the dietary design, embracing uncommon diets with moo sodium, soaked fat and tall calcium, magnesium and potassium and attempting the modern strategies like time confined dinner admissions which work in pair with the circadian cadence are opening modern vistas within the field of non-pharmacological administration of hypertension. Way of life alterations that viably lower blood weight are expanded physical movement, weight misfortune, restricted liquor utilization, unwinding methods of Yoga, Needle therapy, Tai chi, mindfulness-based

stress-reduction program, and Supernatural Contemplation. Non-pharmacological strategies are an necessarily portion of administration of hypertension. It incorporates way of life changes in cultivate of extraordinary diets and decrease of salt, liquor, and immersed fat. Decrease of weight, expanded physical action and time limited feast has moreover been found successful. A few conventional strategies like yoga, needle therapy, and supernatural contemplation are helpful. [23]

Rupal oza et al (2017) conducted a ponder non -pharmacological administration of hypertension. Way of life adjustments are suggested for all patients with hypertension. The American Heart Association/American College of Cardiology way of life administration rule suggests a count calories emphasizing vegetables, natural products, and entirety grains; restricting sodium admissions to less than 2,400 mg per day; and working out three or four times per week for an normal of 40 minutes per session. Other non-pharmacologic methodologies incorporate weight misfortune, tobacco cessation, diminished liquor utilization, biofeedback, and self-measured blood weight checking. For patients with obstructive rest apnea, the utilize of persistent positive aviation route weight has been appeared to make strides blood weight. Dietary supplements such as garlic, cocoa, vitamin C, coenzyme Q10, omega-3 greasy acids, and magnesium have been recommended for bringing down blood weight, but prove is missing. [24]

Anastasios Vamvakis et al (2017) conducted a ponder on advantageous impacts of nonpharmacological intercessions within the administration of fundamental hypertension. It found that lifestyle change could be a energetic strategy that takes training, repeatable mediations and an appropriation period of applying the rules instead of a straightforward and

short-term approach to that way of treatment. Moreover, as tall BP levels happen more in Western sort and created nations, in which living conditions are characterized by a stressful, low physical action, and destitute sustenance quality choices, procedures for progressing quality of life within the common populace are required. These might lead to avoidance as well as to diminishment within the predominance and frequency of EH. In conclusion, in arrange to treat EH based on non pharmacological mediations, a multi factorial approach is required, focusing on at a more changeless and at last less doctor depended, improved quality for nourishment, physical action few times per week, and normal body weight. In spite of the fact that a number of considers have been conducted within the field, more broad and way better outlined investigate is vital to supply way better understanding of the ideal approach. [25]

Section C : Nursing intervention on reduction of hypertension

Kappes et al (2023) conducted a orderly audit on Nurse-led tele-health intercession to discover its adequacy on diminishing hypertension. Hypertension could be a open well being concern for numerous nations thus this precise audit points to synthesize accessible prove on the viability of nursing-led tele-health mediations in decreasing blood weight in hypertensive patients. The World Well being Organization has set up a worldwide objective to decrease the predominance of non- communicable maladies, counting hypertension, which is related with cardiovascular malady. Inaccessible nursing mediations can possibly reduce the burden on the healthcare framework andadvance a more beneficial populace. [26]

Bulto et al (2023) conducted a survey pointed to examine the viability of nurse-led mediations vs. normal care on hypertension administration, way of life conduct, and patients' information of

hypertension and related chance components. The generally pooled information illustrated that nurse-led mediations may diminish systolic blood weight and diastolic blood weight compared with regular care. The length of intercessions contributed to the greatness of blood weight diminishment. Nurse-led intercessions had a positive affect on way of life conduct and viably altered slim down and physical movement, but the impact on smoking and liquor utilization was conflicting. This audit uncovered the useful impacts of nurse-led mediations in hypertension administration compared with normal care. Integration of nurse-led intercessions in schedule hypertension treatment and avoidance administrations seem play an critical part in lightening the rising worldwide burden of hypertension. [27]

Judith et al (2022) conducted a consider on Making strides hypertension control and cardiovascular well being: An critical call to activity for nursing. To create a bound together "Call to Activity for Nurses" to make strides control of hypertension and cardiovascular well being and give data and assets to execute this call. This paper traces parts that enlisted medical caretakers, progressed hone medical attendants, schools of nursing, proficient nursing organizations, quality change medical caretakers, and nursing analysts can play to control hypertension and anticipate CVD within the Joined together States. It portrays evidence-based intercessions to make strides cardiovascular well being and diagrams activities to bring hypertension and CVD to the bleeding edge as a national need for nursing. Connecting Prove to Activity. Evidence-based intercessions exist for medical caretakers to lead endeavors to avoid and control hypertension, in this way avoiding much CVD. Medical attendants can take activities in their communities, their healthcare setting, and their organization to interpret these intercessions into real-world hone settings. [28]

Alves et al (2021) conducted an expository and interventional planned quantitative consider was to evaluate the impact of an instructive intercession performed by medical attendants for mental alteration to incessant illness in patients with hypertension. Information collection was carried out in 329 members with inveterate hypertension, by applying the Mental Alteration to Illness Scale (MADS) some time recently and 1 month after the instructive nursing mediation. The victory rate of the intercession shifted from 26.9% (within the submission to the inevitable subscale) to 44.6% (for the on edge concern subscale). Members were more likely to be rationally "unadjusted" to hypertension on the off chance that they lived with other family individuals, had an dynamic proficient circumstance some time recently the determination of hypertension, still had an dynamic proficient circumstance presently, were beneath 65 a long time ancient, had a shorter time to conclusion (1–2 a long time), and measured blood weight less routinely. The instructive intercession performed by medical caretakers is pertinent for the mental alteration of hypertensive patients, contributing to expanded information, as well as advancement in preventive and self-care hones, encouraging the encounter of the health/disease move handle. [29]

Vedanthan et al (2020) conducted a ponder to assess the impact of a nurse-based hypertension administration program in Kenya. The essential result degree was alter in systolic blood weight (SBP) over one year, analyzed utilizing piece shrewd straight mixed-effect models with a cut point at 3 months. The cohort comprised of 1051 grown-up patients (cruel age 61 a long time; 65% ladies). SBP diminished altogether from standard to three months (nurse-managed patients: slant –4.95 mmHg/month; clinical officer-managed patients: incline –5.28), with no noteworthy distinction between bunches. DBP too essentially diminished from standard to three months with no contrast between supplier bunches. Maintenance in care at 12 months was 42%.Conclusions:

Nurse-managed hypertension care can essentially move forward blood weight. In any case, maintenance in care remains a challenge. [30]

Clark et al (2020) conducted a audit trials of nurture driven intercessions for hypertension in essential care to clarify the prove base, set up whether nurture endorsing is an critical mediation, and distinguish ranges requiring assist think about. Information extraction Systolic and diastolic blood weight, rates coming to target blood weight, and rates taking anti-hypertensive drugs. Mediation impacts were calculated as relative dangers or weighted cruel contrasts, as suitable, and affect ability investigation by consider quality was embraced., Information union Compared with normal care, intercessions that included a ventured treatment calculation appeared more noteworthy decreases in systolic blood weight. Prove was found of made strides results with nurture prescribes from non-UK healthcare settings. Great quality prove from UK essential well-being care is deficient to bolster broad work of medical attendants within the administration of hypertension inside such healthcare frameworks. [31]

Section D : Effect of warm foot soak therapy

Kurnia et al (2022) conducted a study to analyze the impact of hydrotherapy on blood weight among patients with hypertension through a writing review.The information were analyzed utilizing topical examination. The information were at that point evaluated utilizing the Joanna Briggs Organized steps and information extraction was carried out. Agreeing to the discoveries, there are 4 diverse strategies of giving hydrotherapy, specifically utilizing the warm foot douse strategy (17 articles), the sauna strategy (1 article), the whirlpool shower strategy (1 article), and the cryotherapy strategy (1 article). Each strategy of giving hydrotherapy gives diverse comes about. Based on the discoveries, it appears that hydrotherapy can decrease blood weight in

elderly individuals with hypertension. In expansion, giving hydrotherapy by utilizing warm water foot splashes can be especially viable. [32]

Amin et al (2022) conducted a ponder to analyze the impact of warm foot shower treatment on the blood weight and cortisol levels in gestational hypertension. This test ponder encompasses a randomized pre-post-test control gather plan. The control bunch was given 10 mg of nifedipine, whereas the intercession bunch was given 10 mg of nifedipine and a warm water foot shower at 40-43oC for 15 minutes for 14 continuous days. Pre-post cortisol levels were measured with the ELISA strategy cortisol test. It found that warm water foot bath treatment successfully diminished systolic blood weight within the intercession gather, which was 43 mm Hg compared to the control gather, 19 mm Hg ($p<0.05$). Diastolic blood weight within the intervention group was 15.5 mmHg compared to the control group's 6.5 mmHg ($p<0.05$), and cortisol levels within the mediation gather: 48.1 ng/ml compared to the control 14.5 ng/ml ($p<0.05$). It concluded that warm water foot shower treatment at 40-43oC for 15 minutes for 14 sequential days decreases systolic blood weight by diminishing cortisol levels in hypertensive pregnant ladies. [33]

Amin et al (2022) conducted a think about to analyze the impact of warm foot shower treatment on the blood weight and cortisol levels in gestational hypertension. The control gather was given 10 mg of nifedipine, whereas the mediation bunch was given 10 mg of nifedipine and a warm water foot shower at 40-43oC for 15 minutes for 14 successive days. Pre-post cortisol levels were measured with the ELISA strategy cortisol test. A warm water foot shower treatment viably diminished systolic blood weight within the intercession bunch, which was 43 mm Hg compared to the control bunch, 19 mm Hg ($p<0.05$). Diastolic blood weight within the mediation bunch was 15.5 mmHg compared to the control group's 6.5 mmHg ($p<0.05$), and cortisol levels within the mediation gather: 48.1 ng/ml compared to the control 14.5 ng/ml ($p<0.05$). Warm water foot

shower treatment at 40-43oC for 15 minutes for 14 sequential days decreases systolic blood weight by diminishing cortisol levels in hypertensive pregnant ladies. [34]

Puskesmas Kolser et al (2020) conducted a think about to decide the impact of warm water foot shower to diminish blood weight in elderly hypertensive in working zone. Information were collected utilizing perception sheets and spyghmomanometer to decide the impact of warm water foot shower. Examination of thinks about utilizing combined t-test and autonomous t test. The comes about appeared no noteworthy contrasts in systolic and diastolic blood weight some time recently and after the warm water foot shower. Foot drench utilizing warm water is anticipated to be an elective treatment, since it is effortlessly accessible, cheap and commonsense. [35]

Murwidi IC et al (2019) conducted a think about to decide the adequacy of warm water foot douse and Benson unwinding procedures combination in diminishing blood weight as a therapeutic treatment to the hypertension patients. The result appeared that there was a critical distinction between pre (162.53Â±16.90mmHg) and post (154.33Â±19.06mmHg) systolic blood weight cruel, p-value was 0.000, systolic blood weight meanÂ at to begin with 30 minutes after post-test was 146.00Â±18.49 mmHg (p=0.000), moment 30 minutes was 139.93Â±15.98 mmHg (p=0.000), third 30 minutes was 136.33Â±14.06 mmHg (p=0.000) and fourth 30 minutes was 133.47Â±14.59 (p=0.000). There was a critical distinction between pre (95.10Â±9.65mmHg) and post (90.00Â±9.47mmHg) diastolic blood weight cruel, p-value was 0.003, post diastolic blood weight cruel at to begin with 30 minutes was 86.00Â±7.70 mmHg (p=0.000), moment 30 minutes was 86.73Â±7.06 mmHg (p=0.000), third 30 minutes was 84.40Â±5.64 mmHg (p=0.000) and fourth 30 minutes was 83.47Â±5.38 (p=0.000). It can be concluded that combination of warm water foot splash and Benson unwinding strategies is successful to diminish blood weight of hypertensive persistent. [36]

Wantiyah wt al (2018) conducted think about analyzed the impact of foot dousing treatment with warm water on blood weight in elderly. Foot drenching treatment was drained 5 days inside 15 minutes for each session. Information were analyzed by utilizing subordinate and autonomous t test with certainty interim of 95% ($\alpha = 0.05$). There was noteworthy contrast of blood weight after treatment (p systolic = 0.001; p diastolic = 0.001). In the mean time, there was no critical contrast of blood weight in control bunch (p systolic = 0.682; p diastolic = 0.185). In both bunches, the blood weight of elderly with hypertension declined but higher within the mediation bunch than within the control bunch. There was a noteworthy contrast of blood weight between two bunches (p systolic = 0.001 and p diastolic = 0.001). The unwinding impact of foot drenching treatment invigorates the pituitary organ to discharge endorphin hormone, causing systemic vasodilation. Subsequently, foot splashing treatment utilizing warm water influences the blood weight on elderly with hypertension. [37]

Harnani et al (2017) conducted a consider to find out the effectiveness of drench feet warm water treatment to decrease blood weight within the elderly. The Test were elderly with hypertension in working region of Puskesmas Simpang Tiga Pekanbaru. The information collection procedures were utilized perception and measuring blood weight by utilizing sphygnomanometer. The Comes about appeared that by and large elderly with hypertension were on organize II. Result appeared that cruel blood weight post splash feet warm water treatment was 74,00 and standard deviation was 5, 026, with the systolic P esteem was 0.000 (<0.05) and diastolic P esteem was 0.000 (<0.05). So, it may be expressed that drench feet warm water treatment effective to diminish blood weight in elderly. It is recommended to elderly with hypertension to continuously controlling their blood weight, in the event that there's a rising of

blood weight they might utilizing splash feet warm water treatment to treat hypertension as a complementary treatment, cheap and simple to do freely. [38]

NBS et al (2017) conducted a semi test ponder was conducted to survey the adequacy of foot shower treatment in lessening blood weight among clients with hypertension at chosen healing center among 60 clients. Foot shower treatment was given for 10 minutes twice a day. The pre and post level of blood weight was measured utilizing sphygmomanometer. The discoveries uncovered that there was a tall measurable contrast within the level of blood weight. The pretest cruel level of BP was 141.3, standard deviation is 10.24 and the post test cruel is 126.3, standard deviation is 7.06,'t' test esteem is 32.67 in exploratory gather. In control bunch, the pretest cruel level of BP was 155, standard deviation is 16.27 and the post test cruel is 145.6, standard deviation is 16.26, 't' test esteem is 6.22. The ponder concluded that there was critical diminished in Blood Weight in exploratory gather as compared to the control bunch. This appears that foot shower procedure is viable in hypertensive clients. [39]

Vyas et al (2017) conducted a ponder to assess the impact of HAFB on heart rate changeability (HRV) and blood weight (BP) in sound volunteers. All the subjects experienced as it were one session of HAFB (104-degree Fahrenheit) for the length of 20 min. Appraisals such as Electrocardiography and BP were taken some time recently and after the mediation. There's a critical lessening in systolic-BP (SBP), diastolic-BP (DBP), cruel blood vessel weight (Outline), the cruel of the interim between adjoining QRS complexes or the immediate heart rate (RR interim), the number of interim contrasts of progressive NN interim more prominent than 50 ms (NN50), the proportion determined by isolating NN50 by the full number of NN interim(pNN50), and tall recurrence (HF) band of HRV along side a critical increment in heart rate (HR), low-frequency (LF) band of HRV and LF/HF proportion compared to its standard. This

think about recommend that 20 min of HAFB deliver a noteworthy increment in HR and a critical lessening in SBP, DBP, and Outline whereas creating parasympathetic withdrawal. [40]

Gaps and Trends in Literature

28 studies have been reviewed which published since last 6 years (2017-2023) and arranged in chronological order which helped the researcher to understand what has been already done in the area of interest and to develop the conceptual framework, research methodology. There are various studies reporting the effect of warm foot soak therapy on reduction of hypertension. Even though studies of warm foot soak therapy have been done before it lies in the lower level of evidence hierarchy. So, the researcher intended to carry out it using the highest methodology in the evidence hierarchy in a different setting to contribute to higher level evidence

Summary

This chapter dealt with a review of research and non- research literature related to the present study. It revealed that number of studies were done on effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients. The literature review in this chapter facilitated the investigators in designing and conducting the study.

CHAPTER III

METHODOLOGY

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METHODOLOGY

Research Methodology is the system of methods and systematic way to solve research problem. The significance of research lies in its quality. Therefore, is important to pay due attention to study design and adherence to appropriate study methodology throughout the study to improve the quality of research.

This chapter explains the research approach, research design, research variables, research setting, population, sample, data collection tools/ instruments, description of intervention ethical considerations, pilot study, procedure for data collection and plan for data analysis.

Research approach

Quantitative research approach is found appropriate by the group to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patient.

Research design

Experimental Study design (Randomized Controlled Trial) was adopted for the study. Study was an active controlled, with balanced randomization (allocation ratio was 1:1) in which experimental group only received warm foot soak therapy.

Randomization

Simple randomization with allocation ratio 1:1 was used for study.

Randomization sequence was created by computer generated randomization list with the help of www.randomization.com.[12] Allocation concealment was done to minimize the selection bias of

the researcher. Allocation concealment mechanism adopted was Sequentially Numbered, Opaque Sealed envelopes (SNOSE)[13]. Half of the total envelope contained the intervention to be performed to the study participant which was unknown to the researcher. After enrolling the study participants, intervention assignment was ascertained by opening the sealed envelope.

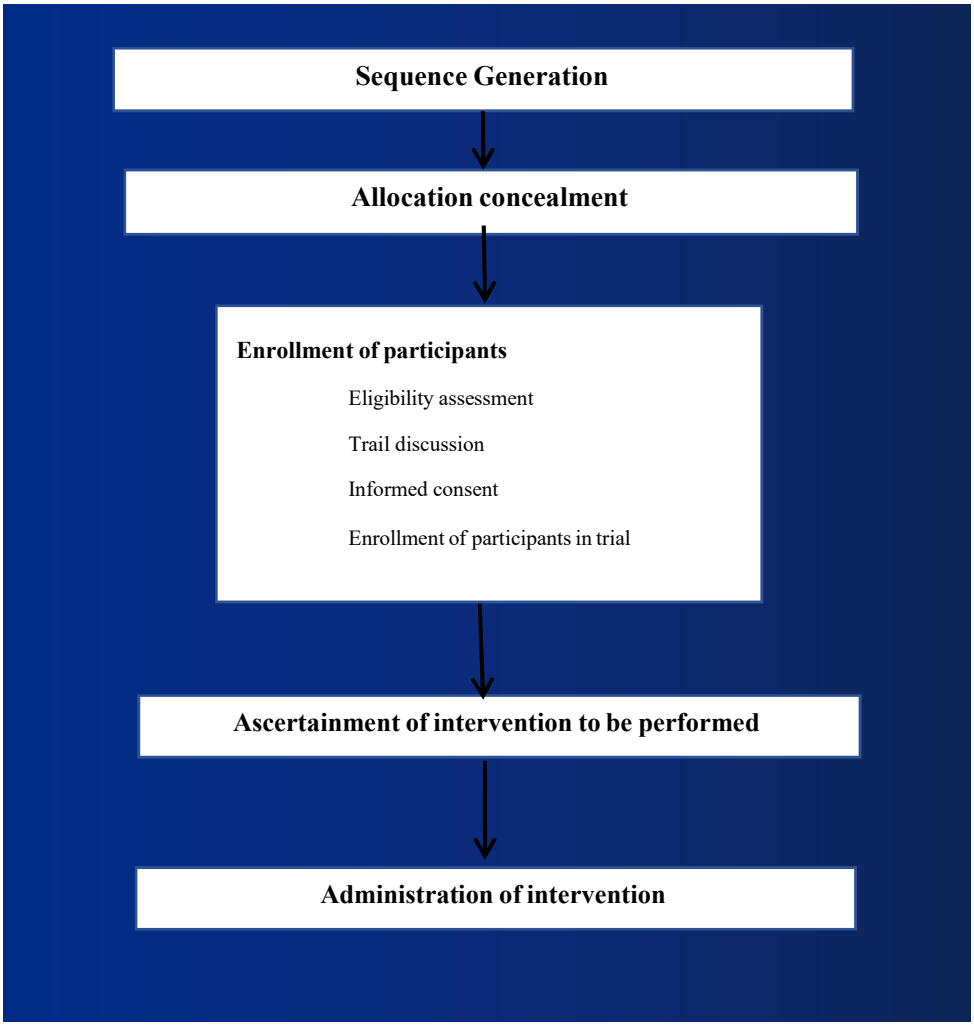

Figure No. 3 : Flow diagram showing randomization process

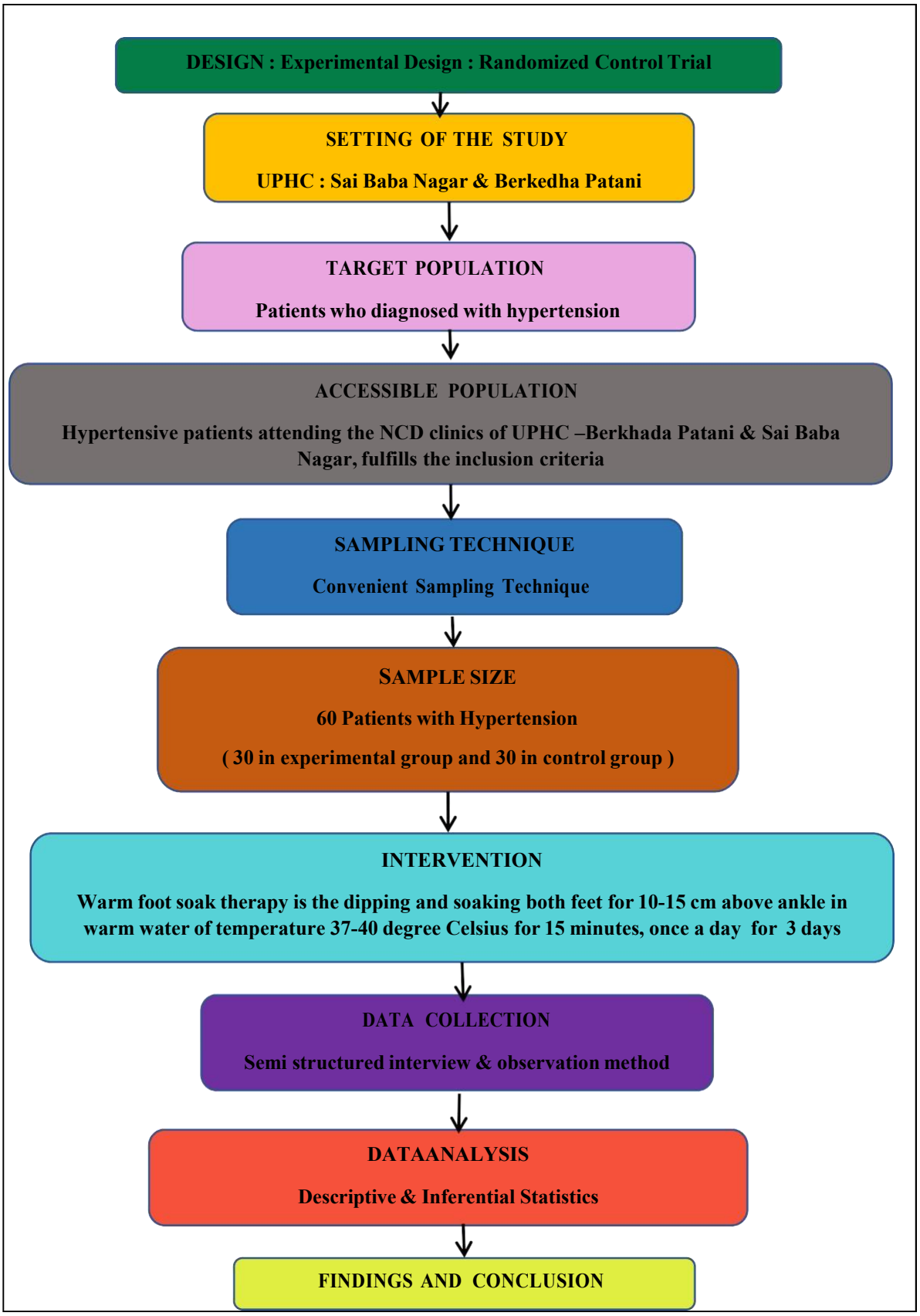
DESIGN : Experimental Design : Randomized Control Trial
SETTING OF THE STUDY
UPHC : Sai Baba Nagar & Berkedha Patani
TARGET POPULATION
Patients who diagnosed with hypertension
ACCESSIBLE POPULATION
Hypertensive patients attending the NCD clinics of UPHC –Berkhada Patani & Sai Baba Nagar, fulfills the inclusion criteria
SAMPLING TECHNIQUE
Convenient Sampling Technique
SAMPLE SIZE
60 Patients with Hypertension
(30 in experimental group and 30 in control group)
INTERVENTION
Warm foot soak therapy is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days
DATA COLLECTION
Semi structured interview & observation method
DATAANALYSIS
Descriptive & Inferential Statistics
FINDINGS AND CONCLUSION

Figure No. 4 : Schematic presentation of research design

Variables under study

1) Independent variables:

Warm foot soak therapy

2) Dependent variables:

Blood pressure

3) Sociodemographic variables

Sociodemographic variables assessed in the study includes Age, Gender, Occupation, Dietary pattern, Smoking habit, History of alcoholism, Anthropometric values (Weight, Height & BMI)

4) Clinical variables

Clinical variables assessed in the study includes duration of hypertension, use of Anti-hypertensive drugs, No.of Anti-hypertensive drugs, presence of co-morbidity, type of co-morbidity

Research setting

Research setting for the study was Urban Primary Health Center : Berkhada Patani & Sai Baba Nagar ,Urban Primary Health centers, India, Madhya Pradesh, Bhopal which provide comprehensive care to people's everyday environment & also conducting NCD (Non-Communicable Disease) Clinics weekly.

Population

1) Target Population :

Patients who diagnosed with hypertension

2) Accessible population :

Hypertensive patients attending the NCD clinics of UPHC –Berkhada Patani & Sai Baba Nagar, fulfills the inclusion criteria.

Sample

1) Inclusion and exclusion criteria

Inclusion Criteria

- Patients who are giving consent for study participation
- Patients who are attending the NCD clinics of UPHC –Berkhada Patani & Sai Baba Nagar
- Adult patient diagnosed with stage 1 & stage 2 hypertension according to the AHA guideline
- Patient who can assume sitting position for a period of 30 minutes at least
- Patient who are conscious and oriented

Exclusion criteria

- Patients who are not willing to participate in study
- Hypertensive patients who are ;

  Diagnosed with stage 3/ hypertensive crisis according to AHA guidelines

Diagnosed with peripheral vascular disorders

Having loss of sensation in the legs

Diagnosed with peripheral neuropathy

Having chronic organ damage(CKD,CHF,CLD,COPD)

Having heat intolerance

Having other lower limb complications like ulcer, lesions ,allergy , trauma ,acute inflammation

2) Sample size (ANNEXURE -10)

Sample size for the present study was calculated using Open Epi Software[14] based on results of previous studies. The parameters assumed in sample size calculation is as follows;

Confidence Interval (2-sided) = 95%, Power = 80%, Ratio of sample size (Group 2/Group 1) =1

Mean and Standard Deviation (Group 1) = 1.243 + 0.641, Mean and Standard Deviation (Group 2) = 0.622 + 0.594.

Calculated Sample size was 34 (17 in experimental group & 17 in control group)

Attrition (non-response) rate set for the present study is 10%

Sample size including non-response rate is 34 (17 in each group)

Researcher rounded off the sample size to 60 (30 in each group)

3) Sampling technique

Convenient sampling technique- A type of non-probability sampling technique was used.

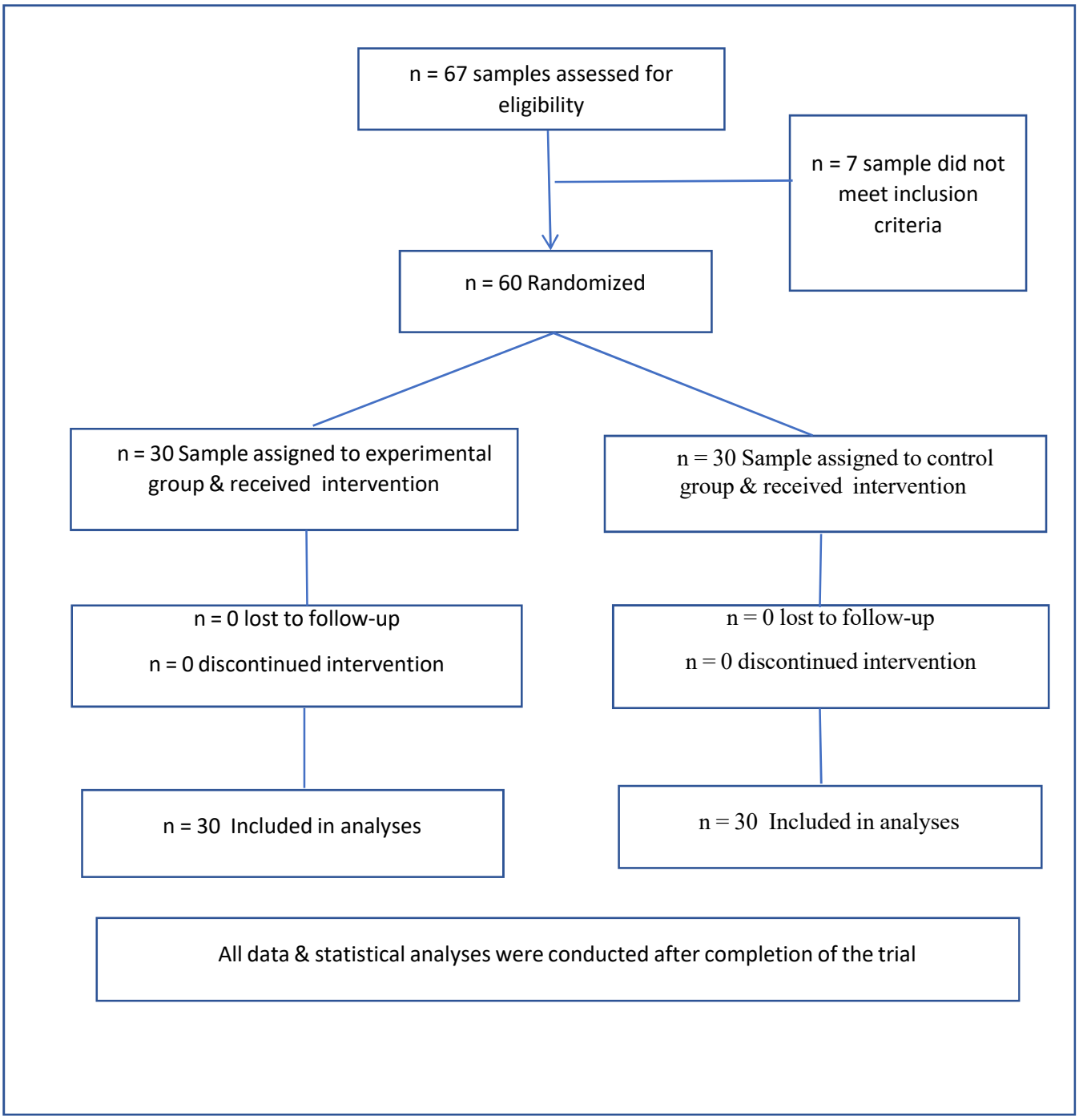
n = 67 samples assessed for eligibility
n = 7 sample did not meet inclusion criteria
n = 60 Randomized
n = 30 Sample assigned to experimental group & received intervention
n = 30 Sample assigned to control group & received intervention
n = 0 lost to follow-up
n = 0 discontinued intervention
n = 0 lost to follow-up
n = 0 discontinued intervention
n = 30 Included in analyses
n = 30 Included in analyses
All data & statistical analyses were conducted after completion of the trial

Figure No. 5 : Consort Diagram of main study

Data collection tools and instruments (ANNEXURE 2)

1) Development and description of tools

The tool of the study was developed after doing extensive literature study and consultation with nursing experts.

The following steps were undertaken in tool development:

1 Extensive review of literature regarding effect of warm foot soak therapy among hypertensive patients

2. Development of sociodemographic and clinical profile sheet based on literature review

3. Content validation

4. Tool modification based on the suggestions of guide, co-guide and experts

5. Tool translation into regional language (Hindi) and consultation with language expert

6. Reliability testing

7. Finalization of tool

Tool of the study includes three parts;

Part -1 : Sociodemographic variables

It consist of participant identification number, age, gender, occupation, dietary pattern, smoking habit, history of alcoholism and anthropometric values (weight, height & BMI)

Part- 2 : Clinical variables

It consist of duration of hypertension, use of Anti-hypertensive drugs, No.of Anti-hypertensive drugs, presence of co-morbidity, type of co-morbidity

Part -3 : Table to record Pre interventional and post interventional blood pressure assessment

it is having two sections;

Section 1 : Pretest & posttest blood pressure assessment of Experimental group

Section 2 : Pretest & posttest blood pressure assessment of Control group

Section 1 : Pretest & posttest blood pressure assessment of Experimental group

- Pre-test blood pressure assessment of selected patient in experimental group using digital sphygmomanometer
- Post-test blood pressure assessment of selected patient in experimental group using digital sphygmomanometer after giving intervention
- Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean

Section 2 : Pretest & Posttest blood pressure assessment of control group

- Pre-test blood pressure assessment of selected patient in control group using digital sphygmomanometer
- Post-test blood pressure assessment of selected patient in control group using digital sphygmomanometer without giving intervention
- Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean

2) Validity and reliability of tools

Content validity of the tool was obtained from 10 experts in the field of nursing (APPENDIX 3)

Individual Item Content Validity Index (I-CVI) was calculated by taking the opinion of score 3 and 4 (highly relevant or quite relevant) and Scale- Content Validity Index (S-CVI) calculated by taking averages of I-CVI. [15]

Acceptable range of I-CVI is 0.78 or above and of S-CVI is 0.90 or above.

All items in sociodemographic sheet having I-CVI greater than 0.78 and S-CVI 092. All items in clinical profile sheet having I-CVI greater than 0.78 and S-CVI 0.98.

Suggestions of experts incorporated and the tool finalized.

Table No. 1 : Validity index of tool

Content validity index	Sociodemographic sheet	Clinical sheet
Item content validity index (I-CVI)	> 0.80	>0.80
Scale content validity index (S-CVI)	0.975	1

Reliability of the tool was assessed during pilot study by collecting data from 10 study participants.

In this study it is checked by Cronbach's alpha, a way of assessing reliability by comparing the amount of shared variance/ covarience[16] . Cronbach's Alpha of 0.868 , hence it is statistically significant and thus tool found to be reliable.

Calibration of research instrument : Digital Sphygmomanometer (ANNEXURE -6)

Table No. 2 : Reliability Cronbach's Alpha

	Value	**P value**
Cronbach's Alpha	0.868	0.005

3)Technique of data collection

Data was collected by semi-structured interview and observation method sociodemographic data and clinical profile data were collected by questioning technique.

Description of intervention (Annexure -7)

Intervention protocol was developed referring books and based on literature review.

Warm foot soak therapy

Warm foot soak therapy is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days.

Ethical considerations

Detailed thesis protocol was submitted to Institutional Human Ethics Committee- Student Research (IHEC-SR) for approval on 15th January 2023 and Letter of Permission (LOP) from IHEC-PGR got on 28th February 2023 with reference number AIIMS/BPL/IHECSR/July/22/MscN/09. Permission obtained from concerned authorities (Principal of Nursing college, AIIMS Bhopal, HOD of CFM department, AIIMS Bhopal and NCD Clinic Incharge , Sai Baba Nagar and Berkheda Patani) prior to the pilot and main study. Written informed consent obtained after giving full disclosure regarding study participation. Anonymity of the participants maintained by assigning code numbers for participants which cannot track back.

Pilot study

Pilot study was conducted in UPHC Sai Baba Nagar and Berkheda Patani for a week from 14/09/2023 to 20/09/2023. Patient who met the inclusion criteria were selected using convenient sampling technique which is a type of non probability sampling technique. 10 subjects were selected conveniently and were randomly allocated to Experimental group and Control group with allocation ratio 1:1, using computer generated randomization list generated from www.randomization.com. Allocation concealment mechanism used in the present study was Sequentially Opaque Sealed envelopes (SNOSE) to minimize researcher's selection bias. Intervention was provided by the researcher only. Experimental group was given with warm foot soak therapy, dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days and control group doesn’t got intervention. Every day before and after 15 minutes of intervention blood pressure assessment taken using digital sphygmomanometer. Blood pressure is taken 3 times within an

interval of 5 minutes and calculated the mean. During pilot study, practicability of the tool, feasibility of study and intervention efficacy was assessed.

Procedure for data collection

The main data collection was from 21/09/2023 to 30/10/2023. Patients attending the NCD clinics of Sai Baba Nagar and Berkheda Patani were selected on basis of the inclusion and exclusion criteria. Informed consent was obtained after full disclosure of study to the participants. 60'study subjects were selected using convenient sampling technique. After screening the patient random allocation into Experimental and Control group. Administered self structured questionnaire for pre-intervention data collection including sociodemographic data and clinical sheet. Pre-interventional blood pressure assessment of both control and experimental group using digital sphygmomanometer and recorded in observation sheet. Intervention : warm foot soak therapy were given only for experimental group. After the intervention, post- interventional blood pressure assessment of both control and experimental group using digital sphygmomanometer and recorded in observation sheet.

Compared the mean blood pressure before and after intervention in both control and experimental group to find out efficacy of intervention.

Plan for data analysis

a. Plan for data analysis includes Descriptive and Inferential statistics.

b. The statistical methods which will be applied for data analysis are:

c. Frequency and percentage distribution will be used for describing sample characteristics.

d. Mean and Standard Deviation the blood pressure among hypertensive patients before the warm foot soak therapy will be done.

e. To assess the effectiveness of warm foot soak therapy among hypertensive patients paired T test will be applied on pre interventional and post interventional mean blood pressure among both control and experimental group.

f. To find association of selected socio demographic and clinical variables with pre interventional change in blood pressure among hypertensive patients Chi square test will be applied.

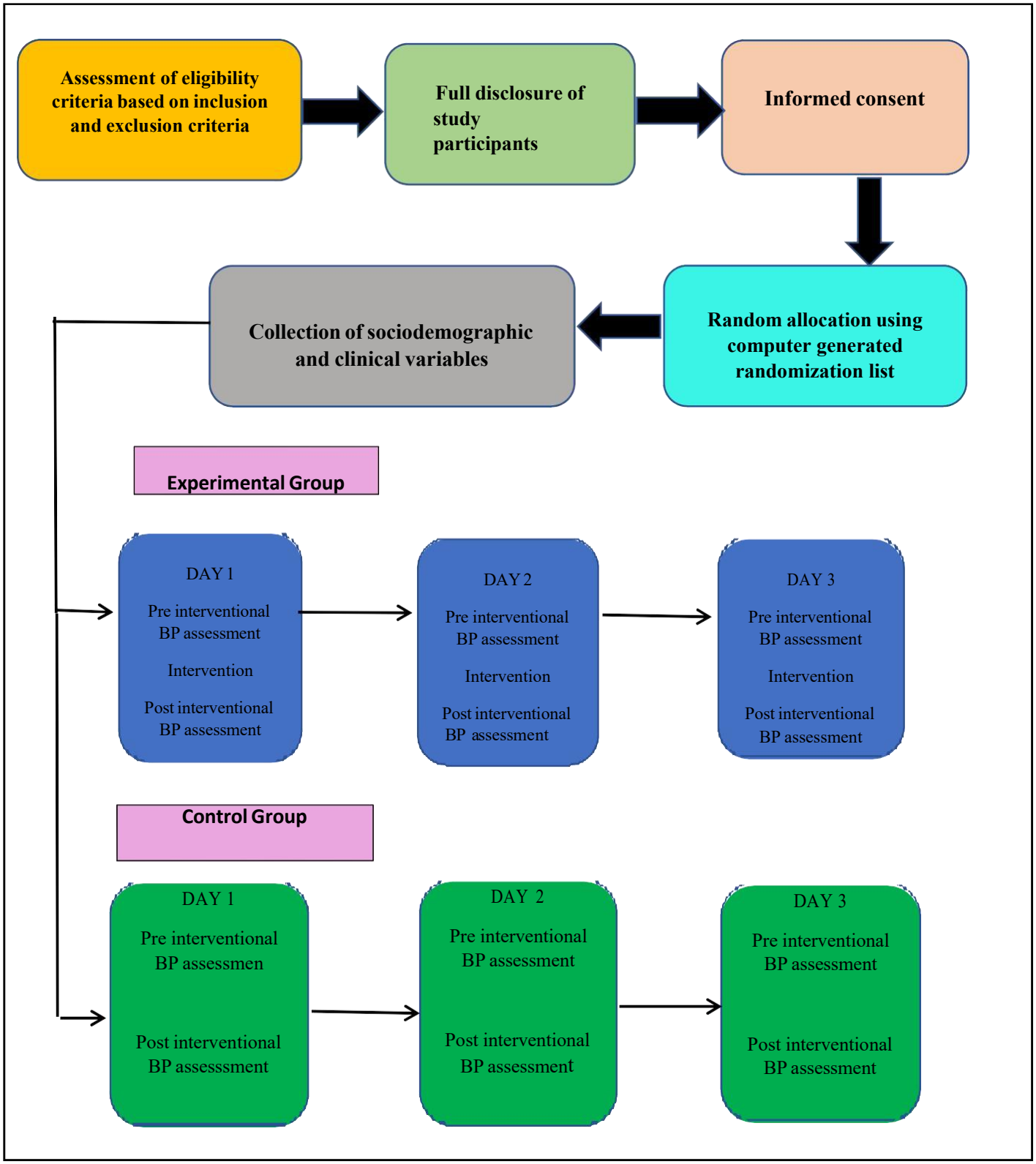

Figure No. 5 : Diagram showing procedure of data collection

Summary

This chapter dealt with methodology adopted for the present study. It includes the research approach ,the research design ,variables under study ,the setting ,population ,sample and sampling technique ,selection ,development and description of tools ,validity and reliability of the tools ,pilot study ,procedure for data collection and plan for data analysis.

CHAPTER IV
RESULT

CHAPTER IV

RESULT

This chapter deals with the analysis and interpretation of collected data to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients.

The investigator applied both descriptive and inferential statistics for analyzing collected data. After entering the collected data to Microsoft Excel, checking and editing of raw data done. Entire data checked for missing data, done and analysis was done using SPSS ver. 27. The study results were analyzed, tabulated and presented based on the data obtained from patients with hypertension, for whom warm foot soak therapy given or not given.

The obtained data were classified as sections as follows:

Section I : Frequency and percentage distribution and homogeneity testing of Socio-demographic variables

Section II : Frequency and percentage distribution and homogeneity testing of clinical variables

Section III : Effectiveness of warm foot soak therapy among hypertensive patients

Section IV : Association of pre-interventional change in blood pressure among hypertensive patients with selected demographic and clinical variables

Section I

Frequency and percentage distribution and homogeneity testing of Socio- demographic variables

This section deals with the frequency and percentage distribution and homogeneity testing of Socio-demographic variables of study participants in Experimental group and Control group.

(N = 60)

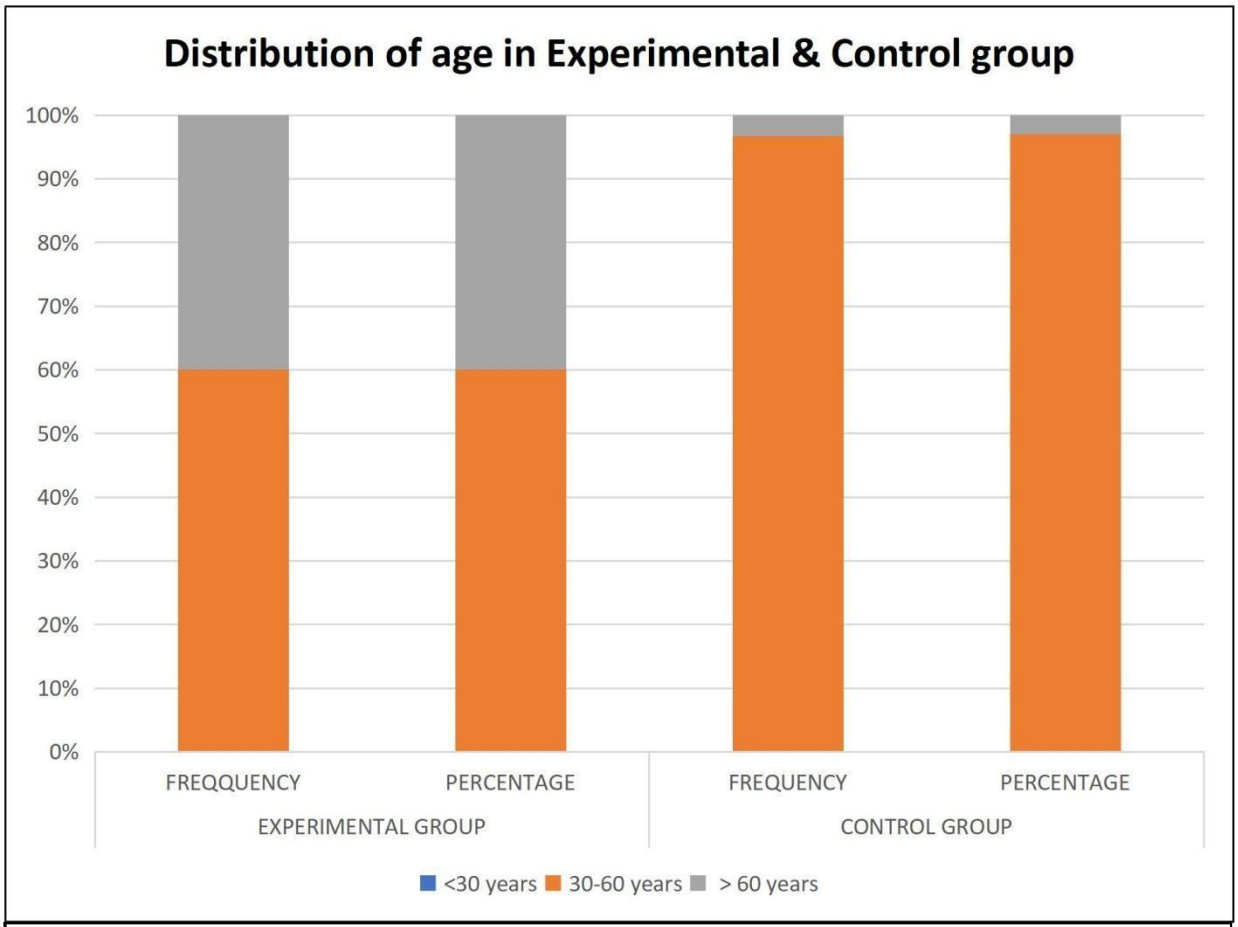

Figure No. 6 : Distribution of age in experimental and control group

Most of the study participants belonged to age group 30-60 years (60% in experimental group and 97% in control group) and then 40 % & 3 % were of age more than 60 years.

(N=60)

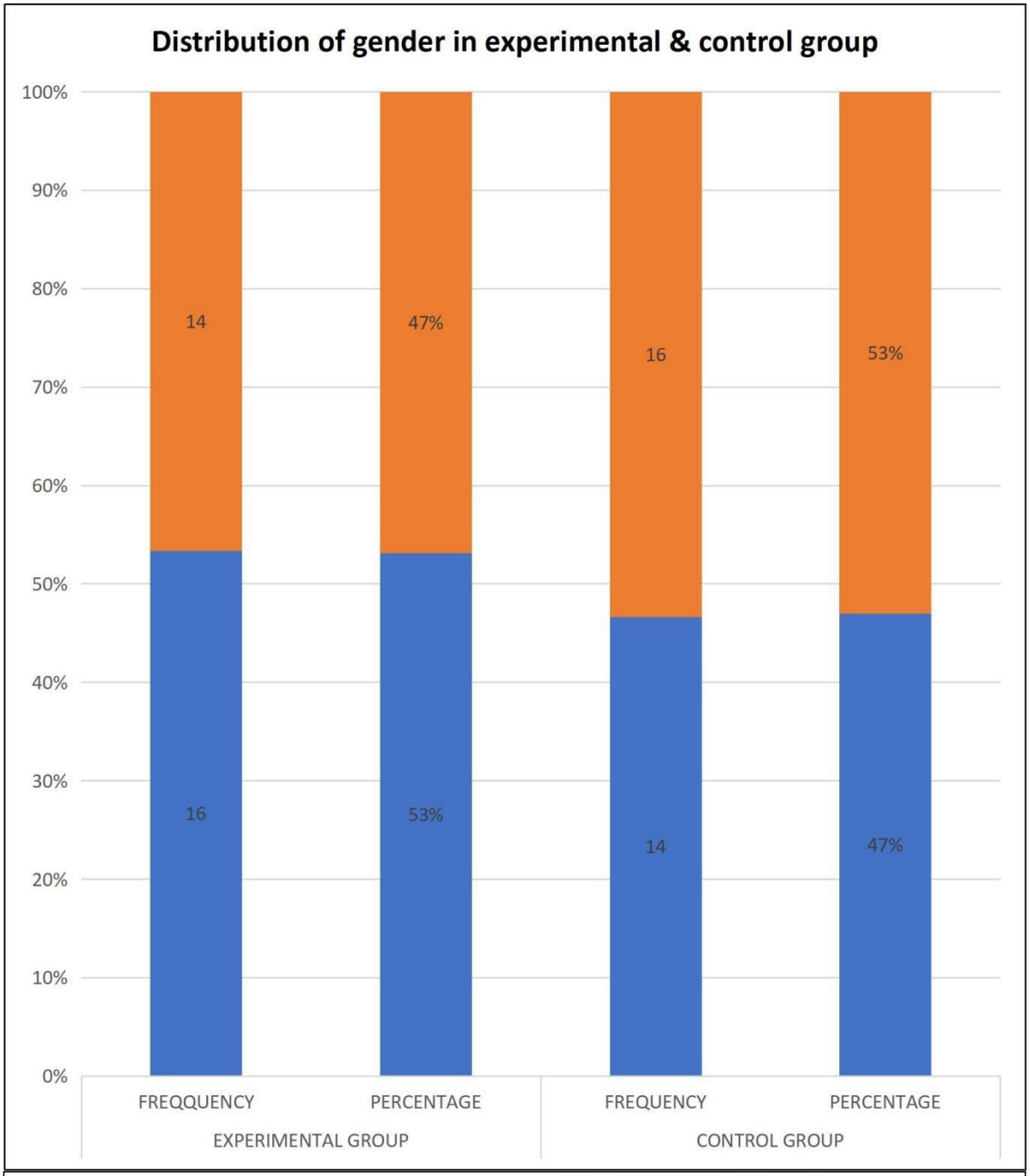

Figure No. 7: Distribution of gender in experimental and control group

From the graph it is clear that, predominant gender in both experimental and control group was male (53%) and then female (53%)

(N=60)

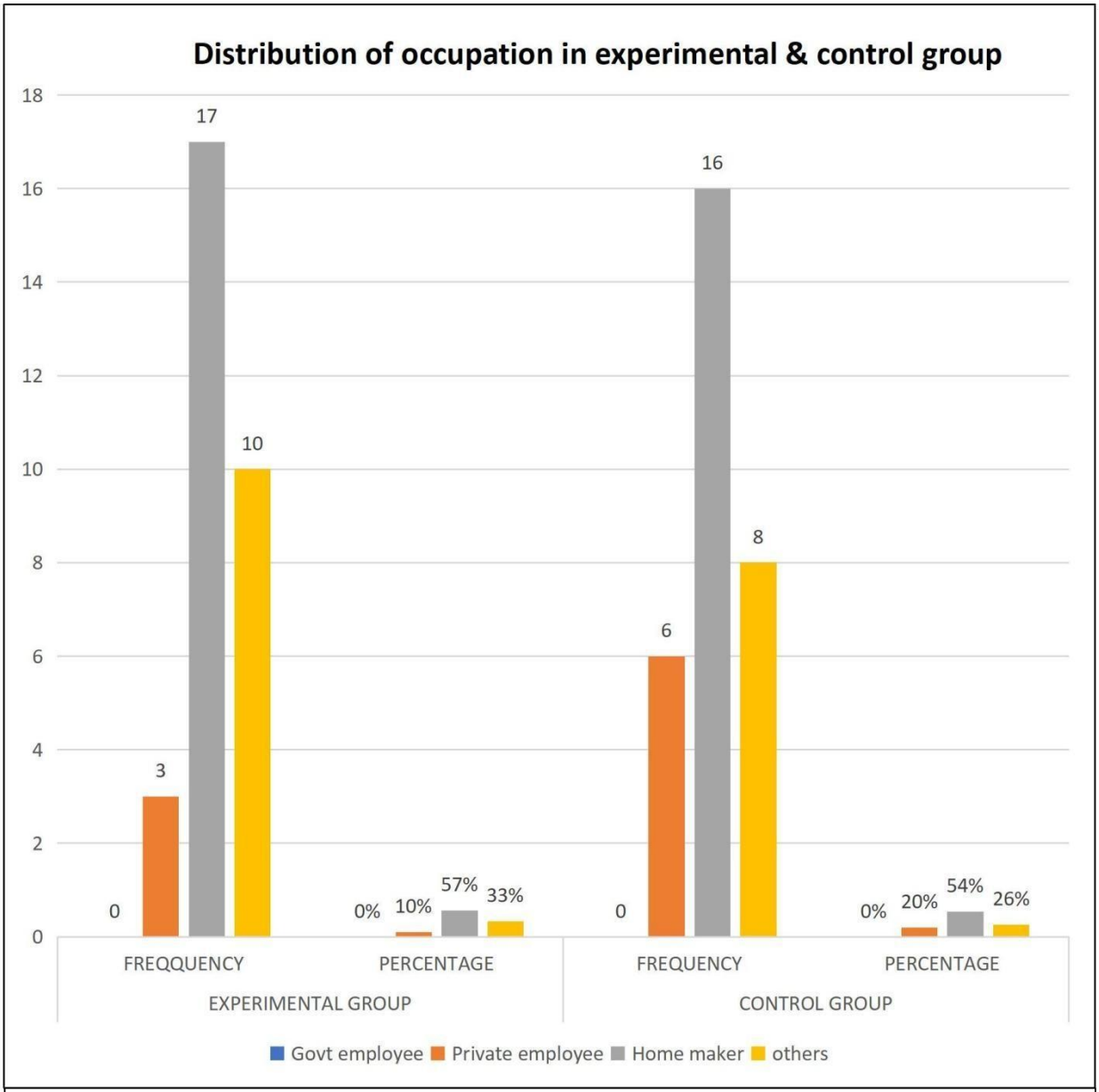

Figure No. 8 : Distribution of occupation in Experimental and Control Group

Majority of study participants were home maker (57% & 54% in experimental & control group) followed by 10% & 26% participants belongs to others category and 10% & 20% were private job

(N=60)

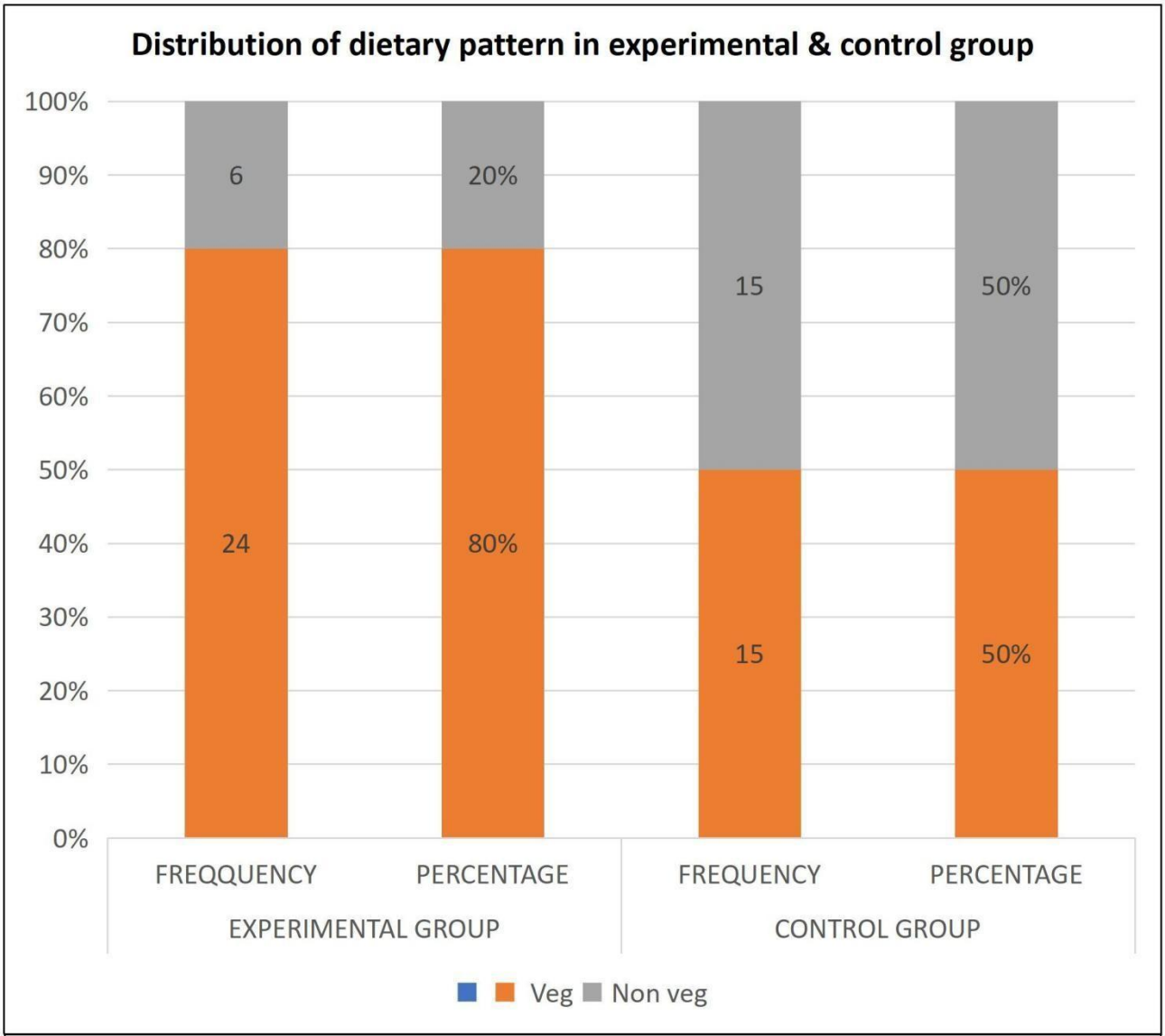

Figure No. 9 : Distribution of dietary pattern in Experimental and Control Group

80 % of study participants in experimental group were vegetarian followed by 20 % were non-vegetarian dietary pattern. In control group 50% were vegetarian & non-vegetarian dietary pattern

(N=60)

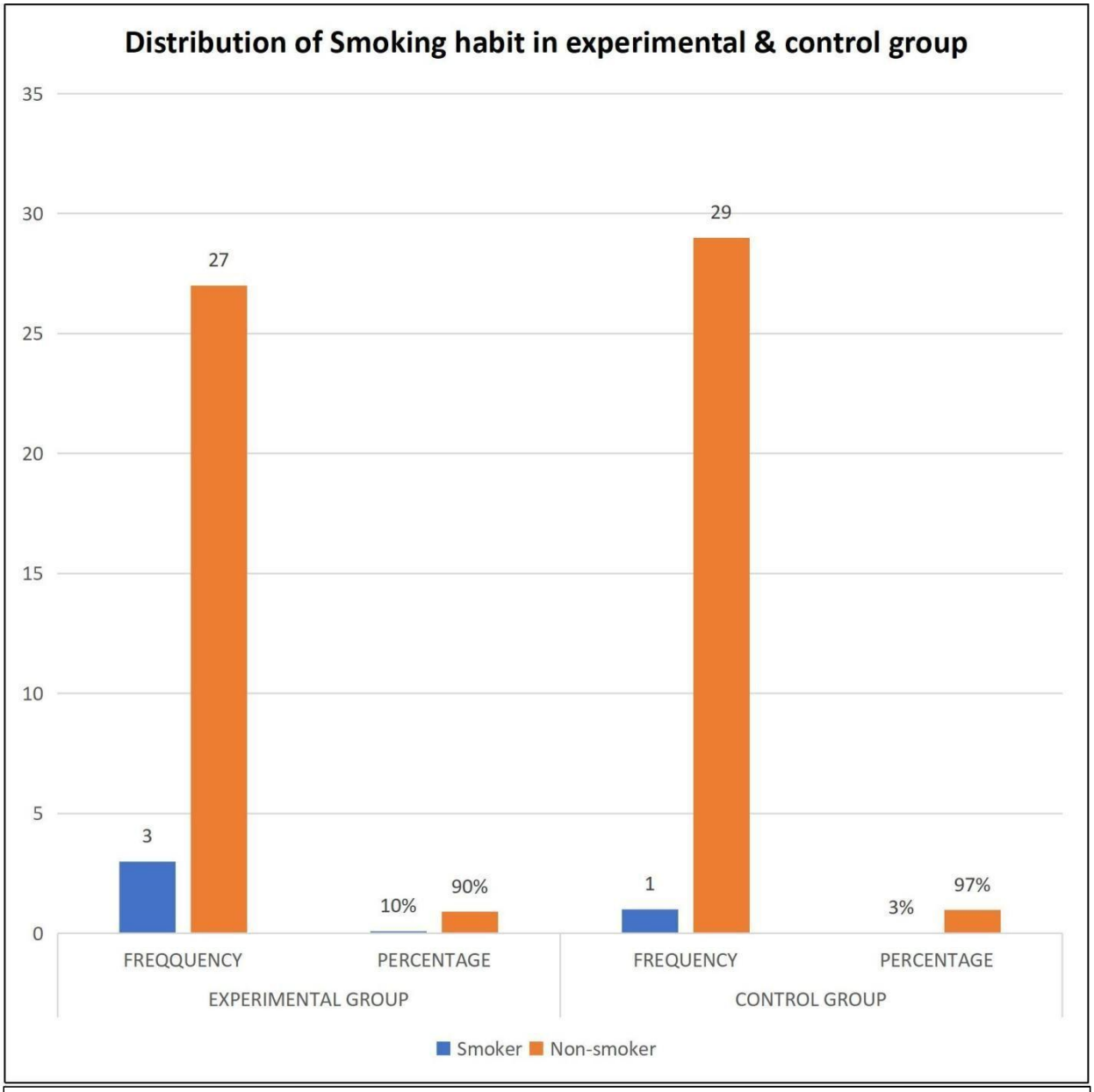

Figure No. 10 : Distribution of Smoking Pattern in Experimental and Control Group

The graph depicts that 90% & 97% of study participants in both experimental and control group were non -smokers followed by 10% & 3% were smokers respectively

(N=60)

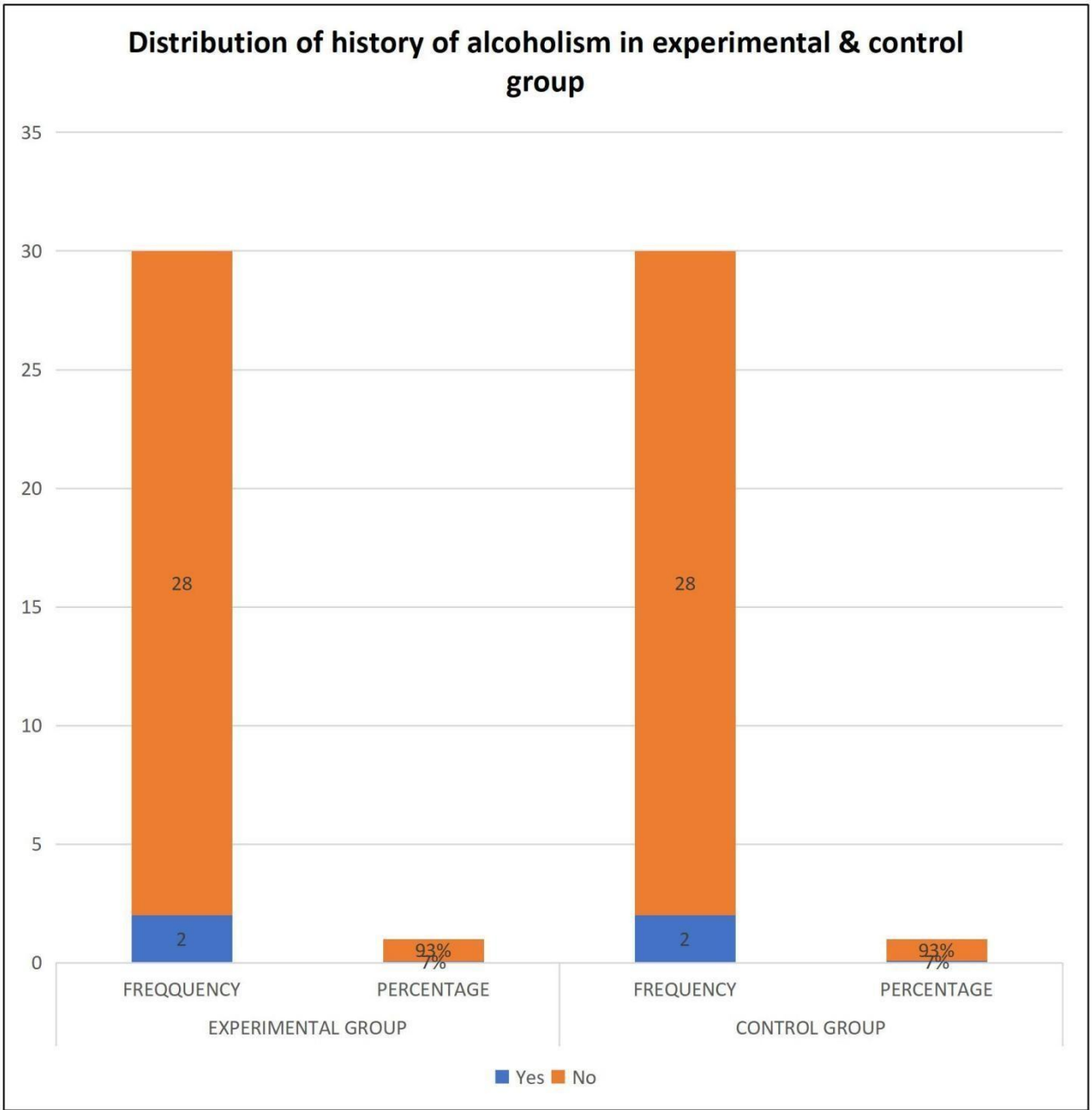

Figure No.11 : Distribution of History of Alcoholism in Experimental and Control Group

Only 7% of participants in both experimental and control group has the History of alcoholism & others (93%) were non-alcoholic.

(N=60)

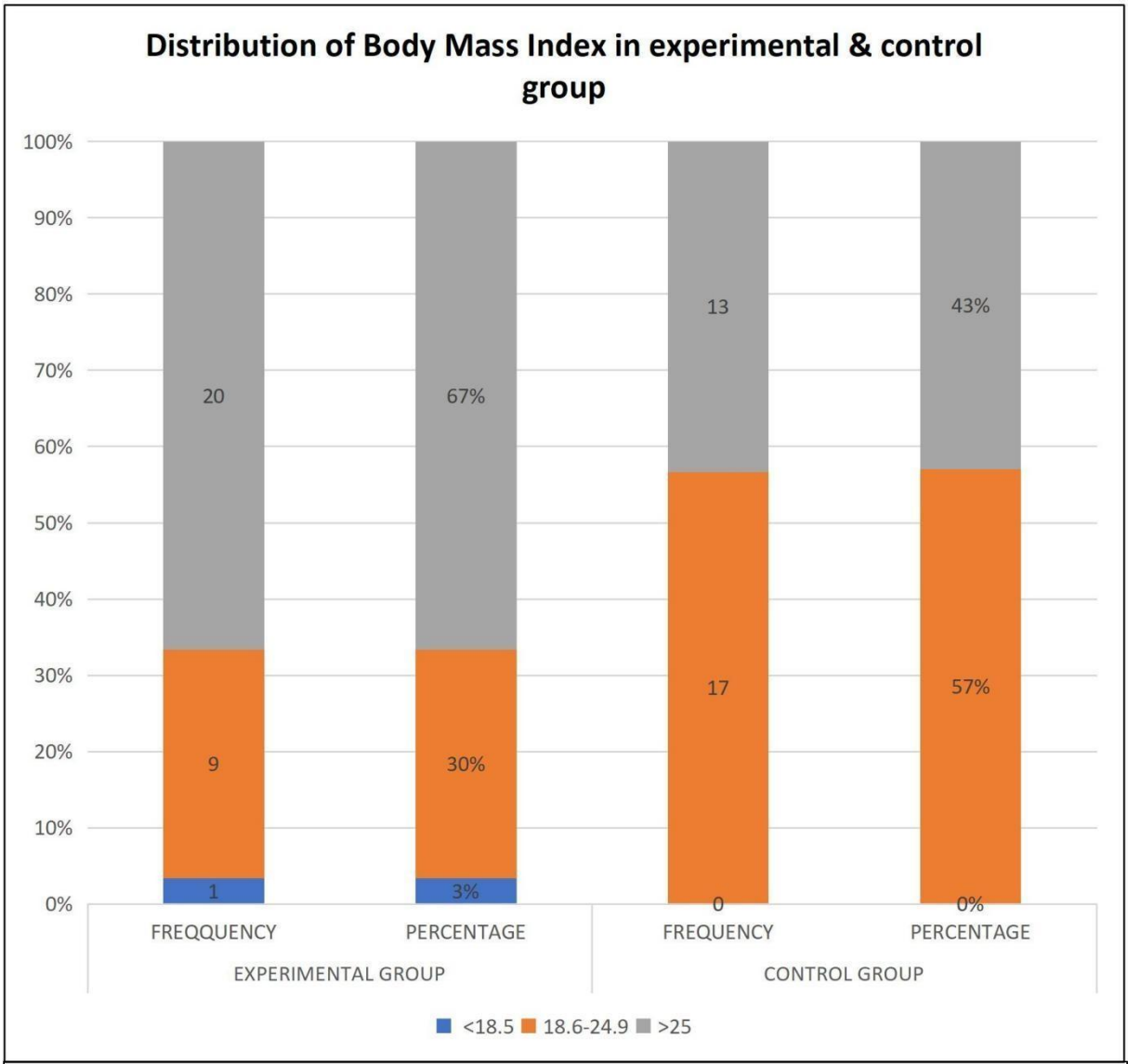

Figure No. 12 : Distribution of Body Mass Index in Experimental and Control Group

From the graph it is clear that 67% of study participants in experimental group were belongs to the Body mass index of > 25 Kg/m2 followed by 30% of BMI < 18.6-24.9 Kg/m2 & only 3% in BMI < 18.5 Kg/m2. In the control group 57 % of study participants has BMI > 25 Kg/m2 and 43% has BMI between 18.6-24.9 Kg/m2.

Table No. 3 : Frequency and percentage distribution and homogenity testing of Sociodemographic variables in Experimental and Control group

(N = 60)

VARIABLE	OPTIONS	EXPERIMENTAL GROUP		CONTROL GROUP		CHI-SQUARE VALUE	P VALUE
		FREQQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE		
AGE	a) <30 years	0	0%	0	0%	4.451	0.439 (NS)
	b) 30-60 years	18	60%	29	97%		
	c) > 60 years	12	40%	1	3%		
GENDER	a) Male	16	53%	14	47%	0.201	0.654 (NS)
	b) Female	14	47%	16	53%		
OCCUPATION	a) Govt employee	0	0%	0	0%	4.066	0.397 (NS)
	b) Private employee	3	10%	6	20%		
	c) Home maker	17	57%	16	54%		
	d) others	10	33%	8	26%		
DIETARY PATTERN	a) Veg	24	80%	15	50%	0.403	0.526 (NS)
	b)Non veg	6	20%	15	50%		
SMOKING	a) Smoker	3	10%	1	3%	0.328	0.439 (NS)
	b) Non-smoker	27	90%	29	97%		
H/o ALCOHOLISM	a) Yes	2	7%	2	7%	0.115	0.735 (NS)
	b) No	28	93%	28	93%		
BMI	a) <18.5	1	3%	0	0%	3.492	0.174 (NS)
	b) 18.6-24.9	9	30%	17	57%		
	c)>25	20	67%	13	43%		

(**F** : Frequency, **NS** : Non significant, BMI :Body Mass Index)

Chi square and p value ($p > 0.05$) in Table No. 3 suggests that there is no significant difference in Experimental and Control group regarding distribution of sociodemographic variables.

Since both the group have similar frequency and percentage distribution of sociodemographic variables and chi square and p value (p value > 0.05) shows the groups are homogenous and comparable.

Section II

Frequency and percentage distribution and homogeneity testing of clinical variables

This section deals with the frequency and percentage distribution and homogeneity testing of Clinical variables of study participants in Experimental group and Control group

(N= 60)

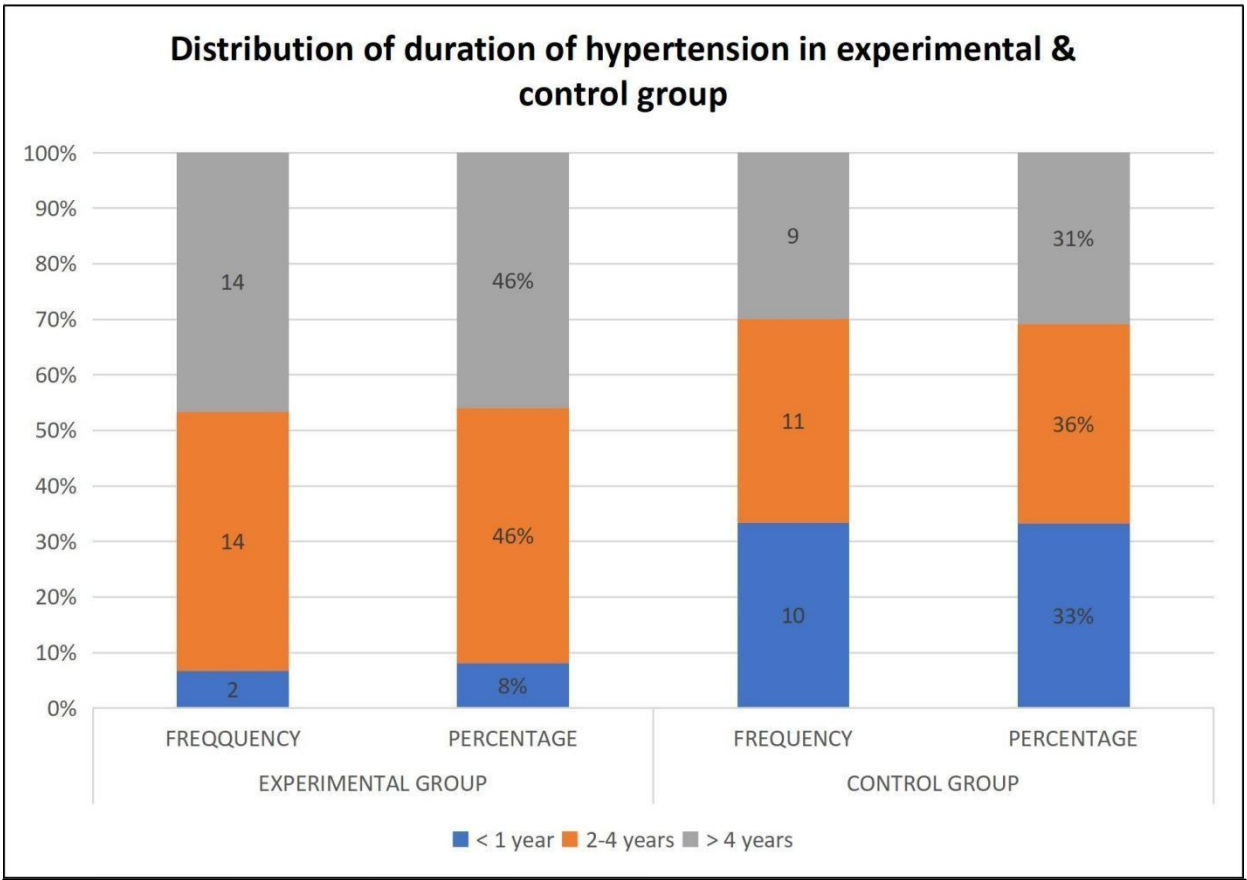

Figure No.13 : Distribution of Duration Of Hypertension in Experimental and Control Group

In experimental & control group 8% & 33% of the study participants has hypertension approximately from 1 year followed by 46 % & 36% study participants has history of hypertension from 2-4 years and 46% & 31% were had > 4 years of hypertensive history.

(N= 60)

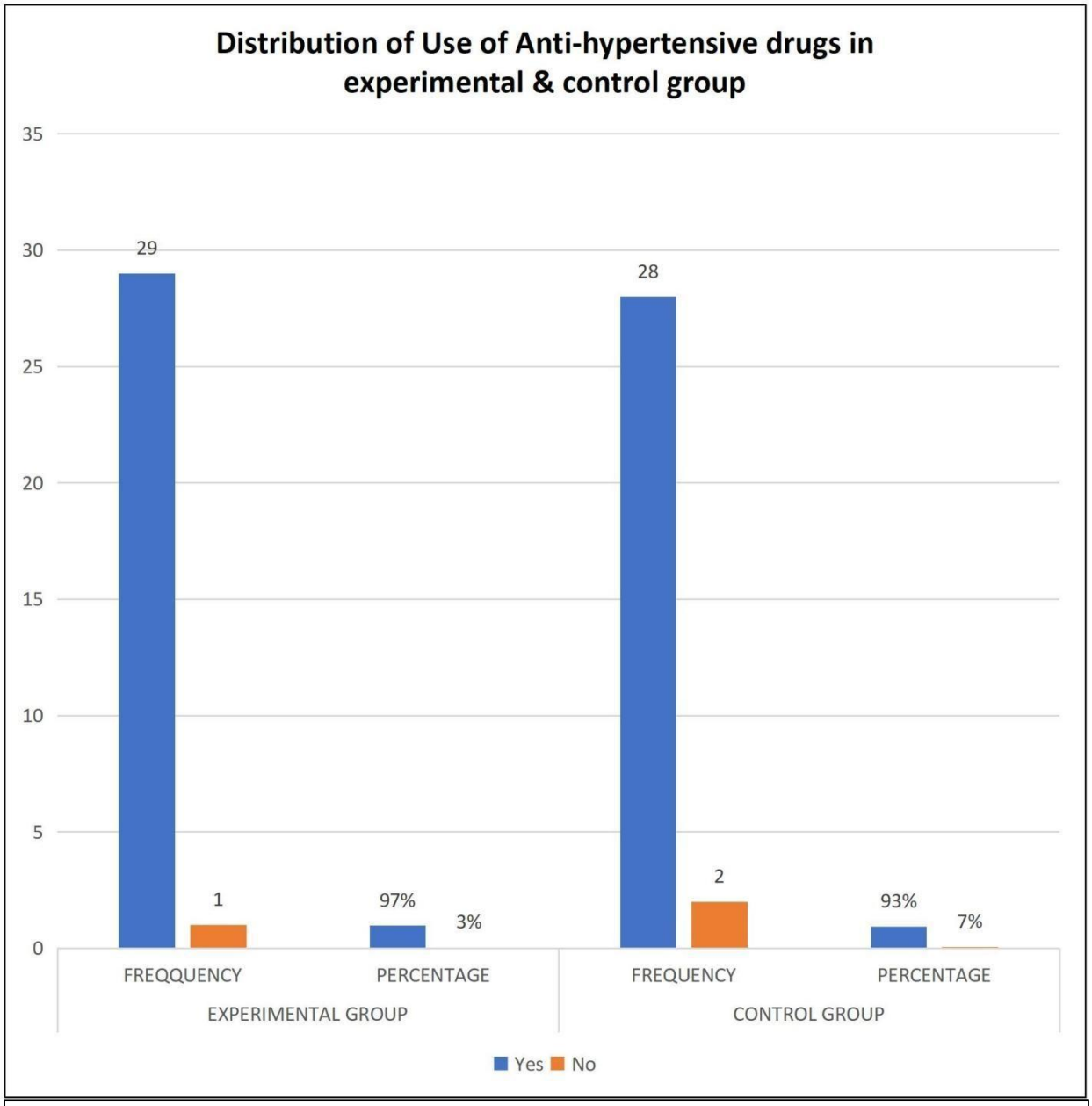

Figure No. 14 : Distribution of use of anti-hypertensive drugs in Experimental and Control Group

Except 7% (C)&3%(E) of study participants all others using Anti-hypertensive drugs as a part of pharmacological management of hypertension

(N= 60)

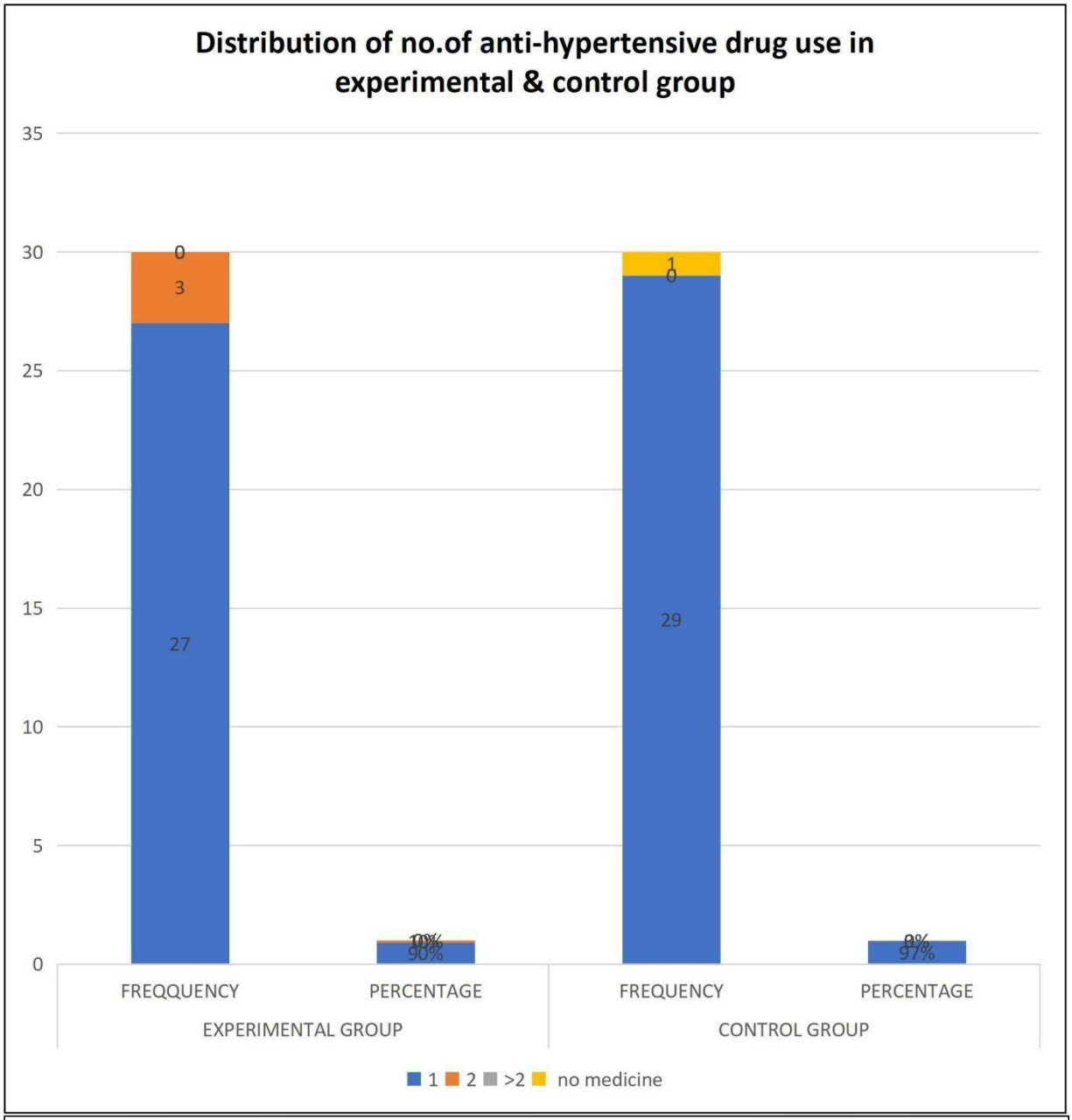

Figure No. 15 : Distribution of No. of Anti-Hypertensive Drugs in Experimental and Control Group

Except 10% of study participants in control group, all others taking only one anti-hypertensive drug, that 3 % is not taking any medications

(N= 60)

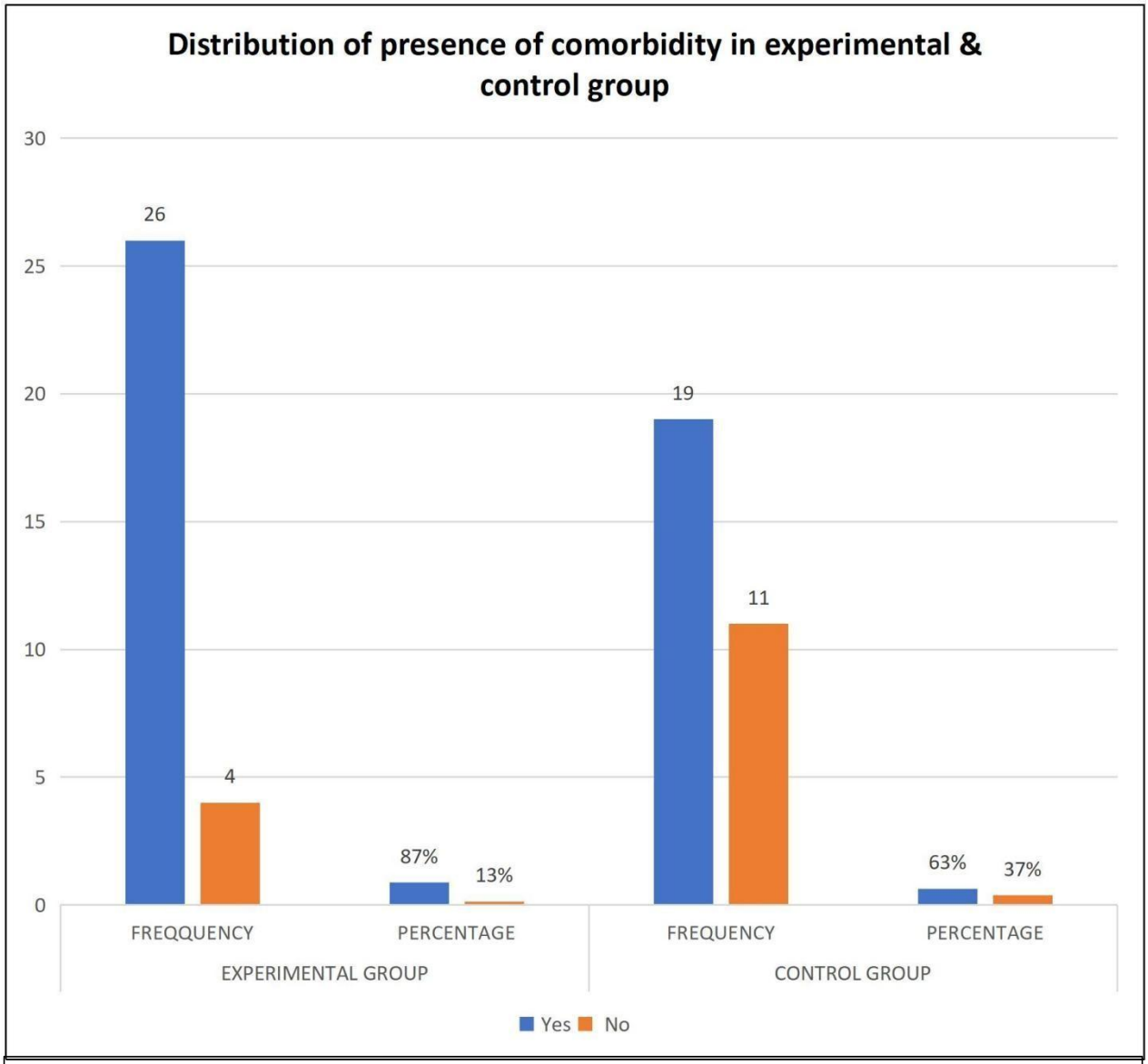

Figure No. 16 : Distribution of presence of co-morbidity in Experimental and Control Group

In experimental group, 87 % of study participants have presence of comorbidity and 13% have no other comorbidity

In control group, 67 % of study participants have presence of comorbidity and 33 % have no other comorbidity

(N= 60)

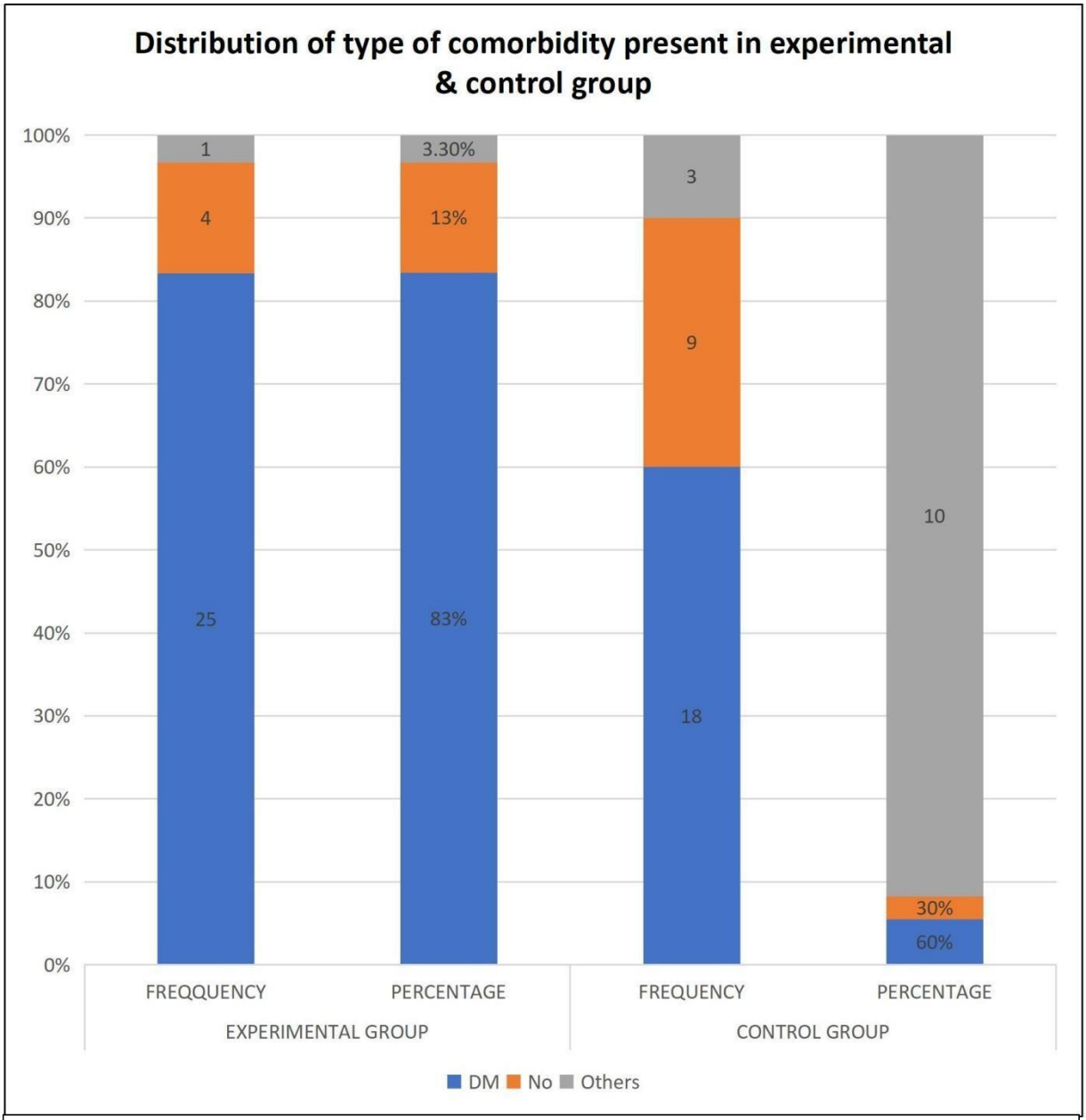

Figure No.17 : Distribution of type of co-morbidity present in Experimental and Control Group

Majority of study participants has 60 % in control group and 83 % in experimental group have diabetes melitus(DM) as the comorbidity, 13% (E) & 30% (C) has no comorbidities present & 3.3% (E) &10% (C) has other comorbidities include hypothyroidism,Glaucoma.

Table No. 4 : Frequency and percentage distribution and homogenity testing of Clinical variables in Experimental and Control group

(N= 60)

VARIABLES	OPTIONS	EXPERIMENTAL GROUP		CONTROL GROUP		CHI SQUARE VALUE	P VALUE
		FREQQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE		
Duration of HTN	a) < 1 year	2	8%	10	33%	11.198	0.243 (NS)
	b) 2-4 years	14	46%	11	36%		
	c)> 4 years	14	46%	9	31%		
Use of Anti-HTN drug	a) Yes	30	100%	29	97%	14.483	0.41 (NS)
	b) No	0	0%	1	3%		
No. of Anti-HTN drugs	a) 1	27	90%	29	97%	0.115	0.735 (NS)
	b) 2	3	10%	0	0%		
	c)>2	0	0%	0	0%		
	d) no medicine	0	0%	1	3%		
Co-morbidities present	a) Yes	26	87%	19	63%	0.017	0.896 (NS)
	b) No	4	13%	11	37%		
Co-morbidities	a) DM	25	83%	18	60%	10.26	0.376 (NS)
	b) No	4	13%	9	30%		
	c) Others	1	3.30%	3	10%		

(**F** : Frequency, **df** : Degree of freedom, **NS** : Non significant, Anti- HTN : Anti- Hypertensive)

Chi square and p value ($p > 0.05$) in Table No. 4 depicts that there is no significant difference in Experimentaland Control group regarding distribution of Clinical variables.

Since both the group have similar frequency and percentage distribution of Clinical variables and chi square and p value (p value > 0.05) shows the groups are homogenous and comparable.

Section III

Effectiveness of warm foot soak therapy among hypertensive patients

This section deals with the descriptive and inferential (Independent t test and paired t test) statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy.

A. Mean and Standard Deviation of Blood pressure among Both Experimental and control Groups Before & After Intervention

B. Independent t test statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy

C. Paired t test statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy

H0 : There will be no significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance

H1 : There will be significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance

Table No. 5

A. Mean and Standard Deviation of Blood pressure among Both Experimental and control Groups Before & After Intervention

(N= 60)

GROUP	PARAMETER	PREINTERVENTIONAL (Mean & SD)	POSTINTERVENTIONAL (Mean & SD)
Experimental	SBP	136.27 ± 8.66	132.72 ± 8.59
	DBP	82.18 ± 5.95	79.07 ± 6.004
Control	SBP	135.44 ± 11.88	135.53 ± 12.01
	DBP	81.27 ± 7.01	81.57 ± 7.04

(**SD** : Standard Deviation, **SBP** : Systolic Blood Pressure, **DBP** : Diastolic Blood Pressure)

By comparing mean blood pressure before and after intervention among both groups it is evident that the intervention : warm foot soak therapy was effective among hypertensive patients & had a significant change in blood pressure (SBP : 3.55 ± 0.07) (DBP : 3.11 ± 0.054)

Table no.

B. Independent t test statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy

(N=60)

Pair	t value	df	p value
Pre Interventional SBP OF E & C	0.31	58	0.758 (NS)
Pre Interventional DBP OF E & C	0.532	58	0.597 (NS)
Post Interventional SBP OF E & C	-1.044	58	0.301 (NS)
Post Interventional DBP OF E & C	-1.497	58	0.144 (NS)

(**SBP** : Systolic Blood Pressure , **DBP** : Diastolic Blood Pressure, **E** : Experimental, **C** : Control, **t value** : Independent t test value, **df** : Degree of freedom, **NS** : Not Significant)

There is no significant diffrence were found in pre interventional and post interventional SBP & DBP among experimental and control group at level of significance 0.05

Table no.

C. Paired t test statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy

(N= 60)

Pair	Mean Difference	Standard Deviation	t Value	df	P Value
Pre SBPE-Post SBPE	3.5546	1.17	16.629	29	0.01 (S)
Pre DBPE-Post DBPE	3.118	1.6	10.673	29	0.01 (S)
Pre SBPC-Post SBPC	-0.916	1.475	-0.34	29	0.736 (NS)
Pre DBPC-Post DBPC	-0.2793	0.548	-2.75	29	0.173 (NS)

(**Pre SBPE** : Pre interventional Systolic Blood Pressure of Experimental group, **Post SBPE** : Post interventional Systolic Blood Pressure of Experimental group, **Pre DBPE** : Pre interventional Diastolic Blood Pressure of Experimental group, **Post DBPE** : Post interventional Diastolic Blood Pressure of Experimental group, **Pre SBPC** : Pre interventional Systolic Blood Pressure of control group, **Post SBPC** : Post interventional Systolic Blood Pressure of Control group, **Pre DBPC** :Pre interventional Diastolic Blood Pressure of control group, **Post DBPC** : Post interventional Diastolic Blood Pressure of Control group, **t value** : paired t test value, **S** : significant, **NS** : Not Significant, **df** : degree of freedom)

From the table its clear that calculated t value is more than tabulated t value for pair 1 & 2 (16.629& 10.673) that is for experimental group and calculated t value is less than tabulated t value for pair 3 & 4 (-0.34 & -2.75) that is for control grp

Hence we can conclude that intervention (warm foot soak therapy) was effective & H0 rejected & H1 accepted : There will be significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance

Section IV

Association of pre-interventional blood pressure among hypertensive patients with selected demographic and clinical variables

This section deals with the association of pre-interventional blood pressure among hypertensive patients with selected demographic and clinical variables among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy using Chi Sqaure test of statistics .

A. Association of selected sociodemographic variables with pre-interventional blood pressure among hypertensive patients

B. Association of selected clinical variables with pre-interventional blood pressure among hypertensive patients

H2 : There will be significant association between selected socio demographic variables with pre-interventional blood pressure among both groups at 0.05 level of significance

H3 : There will be significant association between selected clinical variables with pre-interventional blood pressure among both groups at 0.05 level of significance

Table no.

Association of selected Clinical variables with pre-interventional blood pressure among hypertensive patients

(N=60)

SOCIODEMOGRAPHIC VARIABLES	EXPERIMENTALGROUP			CONTROLGROUP		
	Chi square Value	df	P value	Chi square value	df	P value
AGE	3.025	2	0.22 (NS)	4.334	3	0.227 (NS)
GENDER	0.81	2	0.66 (NS)	4.817	3	0.816 (NS)
OCCUPATION	1.509	4	0.845(NS)	6.688	6	0.351 (NS)
DIET	6.090	2	0.032 (S)	8.221	3	0.042 (S)
SMOKING	SMOKING IS A CONSTANT			1.099	3	0.77 (NS)
ALCOHOLISM	2.069	2	0.355 (NS)	0.33	3	0.96 (NS)
BMI	2.54	2	0.281 (NS)	4.058	6	0.669 (NS)

(**df** : Degree of Freedom, **NS** : Not Significant, **S** : Significant, **BMI** : Body Mass Index)

Data of chi square value showing no significant association between selected sociodemographic variables except for the dietary pattern: vegetarian diet in both control and experimental group with pre- interventional blood pressure among hypertensive patients at level of significance 0.05

Table no.

Association of selected Clinical variables with pre-interventional blood pressure among hypertensive patients

(N=60)

CLINICAL VARIABLES	EXPERIMENTAL GROUP			CONTROL GROUP		
	Chi square Value	df	P value	Chi square value	df	P value
DURATION OF HTN	3.156	4	0.475 (NS)	1.772	6	0.939 (NS)
USE OF Anti-HTN DRUG	1.353	2	0.508 (NS)	3.7	3	0.296 (NS)
NO. OF Anti-HTN DRUGS	2.069	2	0.355 (NS)	0.3	3	0.96 (NS)
PRESNCE OF COMORBIDITIES	7.515	2	0.023 (S)	3.625	3	0.305 (NS)
TYPE OF COMORBIDITY	8.957	4	0.062 (NS)	7.755	6	0.257 (NS)

(**df** : Degree of Freedom, **NS** : Not Significant, **S** : Significant)

Data of chi square value showing no significant association between selected Clinical variables except for the presence of comorbidity : Diabetes Mellitus(DM) in experimental group with pre-interventional blood pressure among hypertensive patients at level of significance 0.05

Summary

This chapter dealt with the statistical analysis & interpretation of data.The objectives of the study were attained through various statistical method and interpretation .The samples characteristics were dealt with frequencies & percentages. Descriptive statistics was used to analyse the data and inferential statistics was computed to find out the effectiveness of warm foot soak therapy and association of pre-interventional blood pressure with selected socio-demographic & clinical variables.

CHAPTER V
DISCUSSION

CHAPTER V

DISCUSSION

This chapter deals with major findings of the study, Discussion, Limitations of the study, Implications for the study, Conclusion and Recommendations.

Major findings of the study

1. Most of the study participants belonged to age group 30-60 years (60% in experimental group and 97% in control group) and then 40 % & 3 % were of age >60 years
2. Predominant gender in both experimental and control group was male (53%) and then female (53%)
3. Majority of study participants were home maker (57% & 54% in experimental & control group
4. 80 % of study participants in experimental group were vegetarian followed by 20 % werenon-vegetarian dietary pattern and in control group 50% were vegetarian & non-vegetarian dietary pattern
5. Study participants in both experimental and control group were non -smokers followed by 10% & 3% were smokers respectively
6. Only 7% of participants in both experimental and control group has the History of alcoholism & others (93%) were non-alcoholic
7. 7% of study participants in experimental group were belongs to the Body mass index of >25 Kg/m2 followed by 30% of BMI < 18.6-24.9 Kg/m2 & only 3% in BMI < 18.5 Kg.m2

8. In the control group 57 % of study participants has BMI > 25 Kg/m2 and 43% has BMI between 18.6-24.9
9. In experimental & control group 8% & 33% of the study participants has hypertension approximately from 1 year followed by 46 % & 36% study participants has history of hypertension from 2-4 years and 46% & 31% were had > 4 years of hypertensive history
10. Except 7% (Control group) & 3% (Experimental group) of study participants all others using Anti-hypertensive drugs as a part of pharmacological management of hypertension
11. Except 10% of study participants in control group, all others taking only one anti-hypertensive drug, that 3 % is not taking any medications
12. In experimental group, 87 % of study participants have presence of comorbidity and 13%have no other comorbidity
13. In control group, 67 % of study participants have presence of comorbidity and 33 % haveno other comorbidity
14. Majority of study participants has 60 % in control group and 83 % in experimental group have diabetes melitus(DM) as the comorbidity, 13% (Experimental) & 30% (Control) has no comorbidity present & 3.3% (Experimental) &10% (Control) has other comorbidity include hypothyroidism, Glaucoma

Findings related to intervention

1. By comparing mean blood pressure before and after intervention among both groups it is evident that the intervention : warm foot soak therapy was effective among hypertensive patients & had a significant change in blood pressure at level of significance 0.05

2. Mean difference and Standard Deviation of systolic blood pressure in Experimental group before intervention was 136.27 ± 8.6 and after intervention was 130.07 ± 8.95 respectively therefore, a significant difference in systolic blood pressure (6.2 ± 0.35) were found at level of significance 0.005
3. Mean difference and Standard Deviation of diastolic blood pressure in Experimental group before intervention was 82.18 ± 5.95 and after intervention was 77.15 ± 5.78 respectively therefore, a significant difference in diastolic blood pressure (5.03 ± 0.12) were found at level of significance 0.005
4. Mean difference and Standard Deviation of systolic blood pressure in control group before intervention was 135.44 ± 11.88 and after intervention was 135.53 ± 12.01 respectively therefore, no significant reduction in systolic blood pressure were found at level of significance 0.005
5. Mean difference and Standard Deviation of diastolic blood pressure in control group before intervention was 81.27 ± 7.01 and after intervention was 81.57 ± 7.04 respectively therefore, no significant reduction in diastolic blood pressure were found at level of significance 0.005

Discussion

The present study was intended to assess the effectiveness of warm foot soak therapy among hypertensive patients.

1. **Description of socio demographic variables and clinical variables of study participants**

Distribution of demographic variables of subjects shows that the majority of subject belongs to age group 30-60 years in both experimental and control group (60% and 97% respectively). Predominant gender in experimental group was male (53%) and in control group was female(53%). Most of the study participants in both experimental and control group(90% & 97%) were non -smokers followed by were smokers respectively.

Similar distribution was noted in quasi-experimental study conducted by **Judith et al.** (28**) and Alves et al.** (22) where most of the participants in both experimental and control group was age 30 and above.

In the clinical variables distribution table shows that majority of study participants in experimental and control group were under anti-hypertensive medication (97% and 93% respectively). Majority of study participants in control and experimental group (60 % and 83%) have diabetes mellitus (DM) as the comorbidity. 13% (Experimental) & 30% (Control) has no co-morbidity present & 3.3% (Experimental) &10% (Control) had other co-morbidity such as hypothyroidism,Glaucoma.

Frequency and percentage distribution of socio-demographic and clinical variables was obtained. Statistical test for assessing homogeneity, chi-square test/ Fisher Exact Test was done for socio-demographic and clinical variables and found that there is no significant difference in proportions among experimental group and control group. Thus, both the groups are homogeneous and comparable.

2. **Effectiveness of warm foot soak therapy among hypertensive patients before and after intervention.**

By comparing mean blood pressure before and after intervention among both experimental and control groups it is evident that the intervention : warm foot soak therapy was effective among hypertensive patients & had a significant change in blood pressure (SBP : 6.2 ± 0.35) (DBP : 5.03 ± 0.12) at 0.05 level of significance.

Analogous study results and intervention was found in the experimental group of clinical trial done by **Jourabloo N** (45). to assess the effectiveness of warm foot soak therapy. Total of 80 participants randomized into 2 groups (experimental and control) , each with 40 participants. Warm foot soak therapy at 37-40 degree Celsius was given, 3 days for a duration of 20 minutes which was similar to the present study. Significant reduction of blood pressure was noted in experimental group at p = 0.05 using paired t test.

The present study finding was similar to the quasi-experimental study conducted by **Vedanthan et al (2020)** (46) to assess the effect of warm foot soak therapy in reducing the blood pressure among hypertensive patients. Among the 50 participants, 25 was given with 2 days of warm foot soak therapy. Author didn't mention the temperature of warm water. Parametric tests such as paired and unpaired t test were used for statistical testing since data was normally distributed. Study concluded that there was a significant difference in mean blood pressure noted in pre and post mean blood pressure in the experimental group ($p < 0.05$).

Alves et al (2021) (47) reported that warm foot soak therapy is effective in reducing blood pressure. Change in blood pressure of Systolic Blood Pressure was about 4-6 mmHg and

Diastolic Blood Pressure was 2-3 mmHg after the consecutive 5 days treatment of warm foot soak therapy.

Several studies have also reported that warm foot soak therapy is effective in reducing blood pressure. Most of the studies provided warm foot soak therapy for greater than 72 hours and for a duration of 15-20 minutes (22,23).

The current results is well ongoing with the result of a survey conducted by **Kappes et al** (26) as the respondents were perceived warm foot soak therapy to have positive effect to reduce blood pressure among hypertensive patients.

Judith et al (2022) (48) concluded significant reduction in post-test mean score in experimental group than control group found statistically significant at p value = 0.001 (25).

3. Association between selected sociodemographic variables with pre-interventional blood pressure among hypertensive patients

Chi square and p value depicted in table shows that there is no significant association between selected sociodemographic variables except for the dietary pattern: vegetarian diet in both control and experimental group with pre- interventional blood pressure among hypertensive patients at level of significance 0.05.

This is supported by various other studies in which demographic variables are not associated with pre- interventional blood pressure among hypertensive patients at level of significance 0.05. (25,28)

4. **Association between selected clinical variables with pre-interventional blood pressure among hypertensive patients**

Chi square test and p value showing no significant association between selected Clinical variables except for the presence of comorbidity : Diabetes Mellitus (DM) in experimental group with pre-interventional blood pressure among hypertensive patients at level of significance 0.05. No any other clinical variables in either experimental or control group shows association with pre- interventional blood pressure among hypertensive patients.

There is no supporting studies for this association and this result is not consistent with previous study findings.

Strengths of the study

1. Strongest study design- Randomized Controlled Trial which lies at the top of evidence hierarchy was adopted for the study
2. Use of allocation concealment mechanism in random allocation reduced selection bias from the part of researcher
3. Interventions and assessments were provided by the researcher alone ensures equality in assessment and administration of intervention

Limitations of the study

1. Non-probability sampling technique was used in the study
2. Time consuming to complete intervention
3. Limited generalization as the study is done for an acute period

Implications for the study

The researcher has drawn the following implications which is vibrant field of concern to the field of nursing service, Nursing education, Nursing administration and Nursing research.

Nursing service

1. Periodic observation and monitoring of the blood pressure is needed for prompt management and control of the hypertensive patients
2. Nurses can implement and demonstrate warm foot soak therapy as a cost-effective complimentary therapy to decrease the blood pressure among hypertensive patients

2Nursing education

1. Nursing curriculum should emphasize the monitoring of blood pressure assessment for all risk age groups for early detection, proper management and prevention of complications among patients.
2. Curriculum should highlight the importance and benefits of implementing non-pharmacological and complimentary therapies for the hypertension management.
3. Educate the future nurse regarding cost-effective simple nursing interventions like warm foot soak therapy for the management of hypertension

Nursing administration

1. Nurse administrator can supervise and aid other nurses to identify early detection and proper management of hypertension.

2. In-service and continuing education program can be conducted to update knowledge in the management of hypertension, especially regarding the cost-effective non-pharmacological and complimentary nursing interventions along with pharmacological management.

Nursing research

1. Nurse researcher can further explore the nursing interventions which are both pharmacological and non- pharmacological for the means of management of hypertension.
2. Dissemination of information can be done to update the knowledge regarding cost-effective treatment options.

Conclusion

The current study aimed to assess the effectiveness of warm foot soak therapy among hypertensive patients. Warm foot soak therapy found to be effective in reducing the systolic and diastolic blood pressure (p value < 0.05). There were no any significant association noted between sociodemographic and clinical variables with pre-interventional blood pressure except for the dietary pattern : vegetarian diet in both control and experimental group and presence of comorbidity : Diabetes Mellitus (DM) in experimental group among hypertensive patients at level of significance 0.05.

Recommendations

1. Warm foot soak therapy can be incorporated in Non-pharmacological/ complimentary management of hypertension
2. A further study is recommended to find the long term effect of warm foot soak therapy on reducing blood pressure.

Summary

This chapter stated the major findings and discussed them in light of the available literature. Limitations, implications, recommendations and conclusion were stated. Warm foot soak therapy was effective in reducing blood pressure among hypertensive patients, however further studies may be conducted to find the long term effect of warm foot soak therapy on reducing blood pressure.

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ANNEXURES

ANNEXURE 1

LETTER SEEKING PERMISSION TO CONDUCT STUDY

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

Saket Nagar, Bhopal – 462020 (M.P)

Institutional Human Ethics Committee- Student Research (IHEC-SR)

www.aiimsbhopal.edu.in Email: ihecpgr@aiimsbhopal.edu.in

Ref Number: AIIMS/BPL/IHECSR/July/22/MscN/09 **Date:** 28th February 2023

Letter of Permission

Student Investigator: **RENJITHA RAVI** **Nursing College, AIIMS, Bhopal**	**Guide:** **Mrs. Ranjana Verma** **Nursing College, AIIMS, Bhopal** **Co-Guides:** **Dr. Jisa George T, Dr. Ankur Joshi**

AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 7th meeting held on 22nd February 2023 discussed your proposal titled **"A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of Blood Pressure among Hypertensive patients"** and evaluated it for suitability for your dissertation as required for fulfilment of MSc (Nursing).

Following members attended the meeting:

1. Prof. D. K. Pal, Former HoD Community Medicine, GMC, Bhopal……Chairperson
2. Prof. Rajnish Joshi, Professor of General Medicine, AIIMS, Bhopal……Member
3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal……Member
4. Dr. Sunita Athawale, Professor of Anatomy, AIIMS, Bhopal……Member
5. Dr. Girish Bhatt, Addl. Professor of Pacdiatrics, AIIMS, Bhopal……Member
6. Dr. Ujjawal Khurana, Assoc. Professor of Pathology, AIIMS, Bhopal……Member
7. Dr. Ankur Joshi, Assoc. Professor of CFM, AIIMS, Bhopal……Member
8. Mr. Trivesh Goswami, Law Officer, AIIMS Bhopal,……Member
9. Dr. Shashank Purwar, Professor of Microbiology, AIIMS, Bhopal……Member Secretary

The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

Shashank Purwar

Dr. Shashank Purwar
Member Secretary, AIIMS Bhopal IHEC-SR
Professor of Microbiology
AIIMS, Bhopal
Contact Number: 7773010099

सामुदायिक एवं पारिवारिक चिकित्सा विभाग
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www.aiimsbhopal.edu.in head.cfm@aiimsbhopal.edu.in Ph: 0755-2672314

AIIMS/BPL/CFM/OFFICE/LoP/2023/765 22nd Sept. 2023, The Friday

Letter of Permission

Subject: Permission for data collection at UPHC Barkheda pathani & Sai Baba Nagar.

Reference: Request letter from Ms. Renjitha Ravi, Msc. Nursing Student, Dated: 12.09.2023

With reference to the above subject this is to inform you that your request letter for data collection on the research study titled "A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients" from the adult patients who attending the NCD clinic of UPHC Berkheda Pathani & Sai Baba Nagar is granted without any financial implication.

22.09.2023

Prof. & Head
Community & Family Medicine
AIIMS, Bhopal

HEAD
Community and Family Medicine
All India Institute of Medical Sciences
Saket Nagar, Bhopal (M.P.)

To,

Ms. Renjitha Ravi
Msc. Nursing Student (2022-2024 batch)
Nursing College, AIIMS Bhopal

Copy to:

1. Dr. Mamta Verma, Associate Professor, I/c Principal College of Nursing.
2. Dr. Ankur Joshi, Associate Professor, Dept of CFM.
3. Dr. Jisa George, Assistant Professor, Dept. of Oncology Nursing.
4. Mrs. Ranjana Verma, Assistant Professor, Dept. of Medical Surgical Nursing.

ANNEXURE 2

SCREENING TOOL

Date of assessment :

Participant identification

number :Address :

Contact :

Instruction : Encircle the appropriate response

1	Is the adult patient with stage 1 & stage 2 hypertension according to the AHA guideline ?	Yes	No
2	Whether the patient who is attending the NCD clinics of UPHC –Berkhada Patani or Sai Baba Nagar ?	Yes	No
3	Whether the patient who can assume sitting position?	Yes	No
4	Is the patient who is conscious and oriented	Yes	No
5	Whether the patient is willing to participate or giving informed consent for study	Yes	No

Interpretation :-

1	Is the adult patient with stage 1 & stage 2 hypertension according to the AHA guideline ?	Yes (included)	No (excluded)
2	Whether the patient who is attending the NCD clinics of UPHC –Berkhada Patani or Sai Baba Nagar ?	Yes (included)	No (excluded)
3	Whether the patient who can assume sitting position?	Yes (included)	No (excluded)
4	Is the patient who is conscious and oriented	Yes (included)	No (excluded)
5	Whether the patient is willing to participate or giving informed consent for study	Yes (included)	No (excluded)

TOOL OF THE STUDY -ENGLISH

Study title *: "A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients"*

Instructions : Tool of the study includes three parts;

Part A – Socio-demographic sheet

Part B – Clinical profile sheet

Part C – Table to record Pre interventional and post interventional blood pressure assessment

it is having two sections;

Section 1 : Pretest & posttest blood pressure assessment of Experimental group

Section 2 : Pretest & posttest blood pressure assessment of Control group

PART A. Socio-demographic sheet

Instructions : researcher will read thequestions and participants will be instructed to respond appropriately and researcher will be noting it down.

1. Participant identification number :
2. Date of data collection :
3. Age :
4. Gender : a) Male b) Female c) Others
5. Occupation : a) Govt. Employee b) Private Employee c) Home Maker d) Others
6. Dietary pattern : a) Vegetarian b) Non- vegetarian

7. Smoking Habit : a) Smoker b) Non-smoker c) Passive smoker

8. History of alcoholism : a) yes b) no

   If yes, duration of alcoholism (in years) :

   Frequency (per week) :

9. Anthropometric values

   Weight (Kg) :

   Height (cm) :

   BMI (Kg/m2) :

Part B . Clinical profile sheet

Instructions : Researcher will obtain the information through participants response

10. Duration of hypertension (in years) :

11. Use of Anti-hypertensive drugs : a) Yes b) No

    If yes, How many Anti-hypertensive drugs in a day: a) 1 b) 2 c) > 2

12. Co-morbidity present : a) Yes b) No

    If yes, which co-morbid condition are you suffering from :

Part 3. Pre And Post Interventional Blood Pressure Assessment

Section -1 :Pretest & posttest blood pressure assessment of Experimental group

- Pre-test blood pressure assessment of selected patient in experimental group using digital sphygmomanometer
- Post-test blood pressure assessment of selected patient in experimental group using digital sphygmomanometer after giving intervention
- Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean

Day 1 :

EXPERIMENTAL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
EXPERIMENTAL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

Day 2 :

EXPERIMENTAL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
EXPERIMENTAL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

Day 3 :

EXPERIMENTAL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
EXPERIMENTAL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

Section -2 :Pretest & posttest blood pressure assessment of Control group

- Pre-test blood pressure assessment of selected patient in control group using digital sphygmomanometer
- Post-test blood pressure assessment of selected patient in control group using digital sphygmomanometer without giving intervention
- Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean

Day 1 :

CONTROL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
CONTROL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

Day 2 :

CONTROL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
CONTROL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

Day 3 :

CONTROL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
CONTROL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

TOOL OF THE STUDY -HINDI

भाग -1 : जनसांख्यिकीय शीट

1. **प्रतिभागी पहचान संख्या** : .....

2. **आयु वर्षों में** :.....

3. **लिंग** : ○ पुरुष ○ महिला

4. **व्यवसाय** : ○ सरकार। कर्मचारी ○ निजी कर्मचारी ○ गृह निर्माता ○ अन्य

5. **आहार पद्धति** : ○ शाकाहारी ○ मांसाहारी

6. **धूमपान** : ○ धूम्रपान करने वाला ○ गैर-धूम्रपान करने वाला
○ निष्क्रिय धूम्रपान करने वाला

7. **शराबबंदी का इतिहास** : ○ हाँ ○ नहीं

यदि हां, तो शराबबंदी की अवधि (वर्षों में) :.....

आवृत्ति (प्रति सप्ताह) :.....

8. **मानवशास्त्रीय मूल्य**

वजन (किग्रा) :.....

ऊंचाई (सैंटिमीटर) :.....

बीएमआई (किलो/एम2) : ○ <18.5 ○18.6-24.9 ○ >25

भाग 2. क्लिनिकल शीट

9. उच्च रक्तचाप की अवधि (वर्षों में) :.....

10. उच्चरक्तचापरोधी दवाओं का उपयोग : ○ हाँ ○ नहीं

यदि हाँ, तो कितनी उच्चरक्तचापरोधी दवाएँ : ○1 ○2 ○> 2

11. सह-रुग्णताएँ मौजूद : ○ हाँ ○ नहीं

यदि हां, तो आप किस सह-रुग्ण स्थिति से पीड़ित हैं:.....

भाग 3. हस्तक्षेप से पहले और बाद में रक्तचाप का आकलन

खंड -1: प्रायोगिक समूह का पूर्वपरीक्षण और परीक्षणोतर रक्तचाप मूल्यांकन

- डिजिटल स्फिग्मोमैनोमीटर का उपयोग करके प्रायोगिक समूह में चयनित रोगी का पूर्व-परीक्षण रक्तचाप मूल्यांकन
- डिजिटल का उपयोग करके प्रायोगिक समूह में चयनित रोगी के परीक्षण के बाद रक्तचाप का आकलन हस्तक्षेप देने के बाद रक्तदाबमापी
- 5 मिनट के अंतराल में 3 बार रक्तचाप लिया जाता है और माध्य की गणना की जाती है

EXPERIMENTAL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
EXPERIMENTAL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

धारा -2: नियंत्रण समूह का पूर्व परीक्षण और पश्चात रक्तचाप मूल्यांकन

- डिजिटल स्फिग्मोमैनोमीटर का उपयोग करके प्रायोगिक समूह में चयनित रोगी का पूर्व-परीक्षण रक्तचाप मूल्यांकन
- डिजिटल का उपयोग करके प्रायोगिक समूह में चयनित रोगी के परीक्षण के बाद रक्तचाप का आकलन हस्तक्षेप दिए बिना रक्तदाबमापी
- 5 मिनट के अंतराल में 3 बार रक्तचाप लिया जाता है और माध्य की गणना की जाती है

CONTROL GROUP	Time interval	PRE-INTERVENTIONAL BLOOD PRESSURE (mmHg)		POST-INTERVENTIONAL BLOOD PRESSURE (mmHg)	
		SBP	DBP	SBP	DBP
CONTROL GROUP NO. =	5 min				
	10min				
	15 min				
MEAN VALUE					

CERTIFICATE OF LANGUAGE TRANSLATION

TO WHOM IT MAY CONCERN

This is to certify that Ms. Renjitha Ravi, M.Sc Cardiological/ Cardiothorasic Vascular Nursing student of Nursing College, AIIMS Bhopal is conducting research on topic "A randomized control trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients". The Hindi version of research tool for this study is a true and accurate translation of the English version and is valid to collect data for research.

The Secondary School Dist. Dahod Chhapariya Ta. Singvad

Seal & Signature : .....

Name of the language expert : Rami Jashvantbhai Ranchhodbhai

Designation : A.T. Teacher.

Qualification : M.A. B.ed.

Date : 30-09-2023

Place : Chhaparvad.

ANNEXURE 3

LIST OF EXPERTS IN CONTENT VALIDATION

1. **Dr Anurag Bhai Patidar**

   Associate professor, AIIMS Bhopal

2. **Mr. R Velmurugan**

   Assistant Professor, AIIMS Bhopal

3. **Mr. Kumarasamy A P**

   Assistant Professor, AIIMS Bhopal

4. **Mrs. Nimrata Rana**

   Assistant Professor, AIIMS Jodhpur

5. **Mr. Nipin Kalal**

   Assistant Professor, AIIMS Jodhpur

6. **Mrs. Latika Kawarti**

   Assistant Professor, AIIMS Nagpur

7. **Mr. Maneesh Sharma**

   Assistant Professor, AIIMS Rishikesh

8. **Dr Rakesh Sharma**

   Assistant Professor, AIIMS Rishikesh

9. **Mr. Midhun Kumar M**

   Assistant Nursing Superintendent, AIIMS Bhopal

10. **Ms. Nancy Kurien**

    Tutor, AIIMS Jodhpur

ANNEXURE 4

CONTENT VALIDATION LETTER WITH CRITERIA

From, Date :

Ms. Renjitha Ravi

M.Sc. Cardiological/Cardiothorasic Vascular Nursing (Batch 2022-24)

Nursing college, AIIMS Bhopal

To,

……..

……

Subject : Requesting the expert's opinion and suggestion for the content validity of research tool

Respected Sir/ Madam,

I, Renjitha Ravi ,M.Sc. Cardiological/Cardiothorasic Vascular Nursing (Batch 2022-24) student of Nursing College, AIIMS Bhopal. I have selected the topic mentioned below for my dissertation to be submitted as partial fulfillment of Masters in Nursing Degree programme, at the nursing college, AIIMS Bhopal. ***Title of the study : "A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients"***

In this regard I have prepared the following:

It consist of Three parts;

Part -1 : Socio demographic variables

Part- 2 : Clinical variables

Part -3 : Table to record Pre and post interventional blood pressure assessment , its having two sections;

Section 1 : Pretest & posttest blood pressure assessment of Experimental group

Section 2 : Pretest & Posttest blood pressure assessment of control group

Kindly go through the tool and give your valuable remarks and suggestion for any modification needed in the content. I shall be grateful to you for your valuable remarks and suggestion.

Thanking you

Enclosed with

Brief synopsis, research tool, criteria checklist for content validity of the tool, certificate of validation.

Your sincerely,

Ms. Renjitha Ravi

M.Sc. Cardiological/Cardiothorasic Vascular Nursing (Batch 2022-24)

Nursing college, AIIMS Bhopal

GUIDE

Mrs. Ranjana Verma

Assistant professor , Nursing college, AIIMS Bhopal

CO-GUIDE

Dr. Jisa George T

Assistant professor, Nursing college, AIIMS Bhopal

CO-GUIDE

Dr. Ankur Joshi

Associate professor, Dept. of CFM, AIIMS Bhopal

Dr. Mamta Verma

I/C PRINCIPAL , Nursing College, AIIMS Bhopal

CRITERIA CHECKLIST FOR THE VALIDATION OF THE TOOL

Dear Experts,

This study consist Self- structured tool , which consists following: It consist of Three parts;

Part -1 : Socio demographic variables Part- 2 : Clinical variables

Part -3 : Table to record Pre and post interventional blood pressure assessment

its having two sections;

Section 1 : Pretest & posttest blood pressure assessment of Experimental group

Section 2 : Pretest & Posttest blood pressure assessment of control group

ITEM NO:	VERY RELEVANT (4)	RELEVANT TO SOME EXTENT (3)	NEED MODIFICATION (2)	NOT RELEVANT (1)	REMARKS
1.Participant identification number					
2. Age **a) 18-28 years** **b) 29-38 years** **c) 39-48 years** **d) > 49 years**					
3. Gender **a) Male** **b) Female**					
4. Occupation **a) Govt. Employee** **b) Private Employee**					

c) Business **d) Others**					
5. Dietary pattern **a) Vegetarian** **b) Non-vegetarian**					
6. Smoking Habit **a) Yes** **b) No**					
IF YES,					
How long doing smoking ? a) <5 years b) 5-10 years c) > 10 years					
How many cigarettepe rday : a) <5 b) 5-10 c) >10					
7. Alcohol habit : a) Yes b) No					
IF YES ,					
How long doingalcohol drinking : a) <5 years b) 5-10 years					

c) > 10 years					
How many peg perweek : a)<5					

Signature of the Expert **Name and Designation**

PART- 2 : CLINICAL VARIABLES

ITEM NO:	VERY RELEVANT (4)	RELEVANT TOSOME EXTENT (3)	NEED MODIFICATION (2)	NOT RELEVANT (1)	REMARKS
9. Duration of hypertension (inYears) : a) <1 b) 2-4 c) >5					
10. Use of anti-hypertensive drugs a) Yes b) No					
If yes, How many anti-hypertensive drugs : a) 1 b) 2 c) > 2					
9. Co-morbidities: **a) Yes** **b) No**					
Which co-morbidity you are suffering ?					

Signature of the Expert **Name and Designation**

CRITERIA FOR CONTENT VALIDITY -INTERVENTION PROTOCOL

Kindly go through the following content and give your valuable suggestions.

Intervention : WARM FOOT SOAK THERAPY

SL NO.	CONTENT	SATISFIED	NOT SATISFIED	SUGGESTIONS
1.	Warm foot soak therapy is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days			
2.	**Articles** A tray containing : • Insulated foot bath bucket with warm water of temperature 37-40 degree Celsius : To soak feet • Water boiling kettle : To boil water • Water thermometer : To measure water temperature • Two towel : To dry feet & cover the bucket/basin • A digital sphygmomanometer : To assess the blood pressure • Research instrument in the form of observation sheet			
3.	**1. Preparation of environment :-** • prepare a calm and quite environment • provide adequate ventilation and light • maintain patients privacy **2. Preparation of client :-** • provide patient a sitting position with dependent feet • obtain consent from the patient • explain the procedure			

4.	**3.Steps of procedure** • Assess the pre interventional blood pressure (Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean) of patient in sitting position at left upper arm probably • Carry the equipment and screen the patient if necessary • If the feet look dirty ,wash first • Fill the insulated foot bath bucket with warm water until it is half full then measure the temperature of water (37-40 degree Celsius) with a thermometer • Dip & soak feet for 10-15 cm above ankle and then leave it for 15 minutes • Cover the bucket with a towel to maintain the temperature • When finished (after 15 min) ,lift the leg & dry it with a towel			
5.	**4. After care of patient :-** • On completion of treatment remove and clean the equipment • Leave the patient comfortable and chart the treatment • Assessment of post interventional blood pressure			
6.	**5. After care of articles :-** • Discard the water • Do hand washing			

ANNEXURE

CERTIFICATION OF VALIDATION

This is to certify that Questionnaire /Tool constructed by Ms. Renjitha Ravi M.Sc.Cardiological/Cardiothorasic Vascular Nursing (Batch 2022-24) Nursing College, AIIMS Bhopal, to be used in her study titled - “A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients” has been validated by me and is found to be valid/ appropriate with/without suggestion.

Overall Remark :

Signature:

Name of the Expert:
Designation:
Name of the Institution:
Official Seal:

Date:
Place:

ANNEXURE

CALIBRATION CERTIFICATE OF INSTRUMENT

CC-2689

Hi-Tech Laboratory & Services
(A House of Measurement & Calibration)

Shivani Complex, C-4, Vidya Vihar, Opp. Barkatullah University, Bhopal- 462 026 M.P., India
Tel.: 0755 - 2410094, 4235738 Telefax. : 0755 - 2410094
Mobile: 094250 09513 web: www.htls.co.in
e-mail: htlsbpl@hotmail.com / info@htls.co.in

CALIBRATION CERTIFICATE

(Form No. HTLS/QF/7.8.1/01 (Amendment No. 00 Dated 1st January 2020)

ULR : CC268923100004423F	Mechanical Calibration	Certificate Issue Date:	24.04.2023

Certificate No.	Recived on	Recived Condition	Calibration On	Calibration Due	Page No.
HTLS/23/RR/387.01	21.04.2023	working	24.04.2023	23.04.2024 (As per customer requirements)	1 of 1

1)a. Calibrated For:
M/s RENJITHA RAVI
M.Sc Cardiological / Cardiothoracic Vascular
Nursing Student Nursing College,
AIIMS Bhopal (M.P.)

b. Name of Equipment / Instrument
Digital Blood Pressure Apparatus

c. Calibration Location : At Lab

2) Description & Identification of Equipment / Instrument Under Calibrations (EUC):

Manufactured by	Model	Serial No.	Type	Identification No.
Dr. Morepen	BP - 02	---	Digital	---

Range	Least Count	Calibrated Range	Declared Accuracy
40 to 230 mmHg	1 mmHg	upto 230 mmHg	± 3 mmHg

3) Standard / Calibrator & Measuring Equipments Used :

Standard Used	Make	Sr. No./Id No.	Traceability Certificate No.	Validity
Digital Manometer	WACO/ 280	L22120601-03	NABL : CC3172	05.12.2023
Digital Pressure Gauge (-1 to 1 bar)	Jupiter Electronics / HTLS/DPG/04	L23010501-01	NABL : CC3172	04.01.2024
with multifunction Pressure Calibrator.				
The Standards used for calibration were calibrated by using reference standard traceable to National Standard.				

4) Principle / Methodology of Calibration & Procedure :
Methodology adopted for calibration is as per HTLS Procedure No.HTLS/CP/VG-01 . As Per DKD-R-6-1 Standard.

5) Calibration Results :

Sr. No.	Unit	EUC Value	Standard Value Average	Deviation	Expended Uncertainty (±)
ASCENDING					
a.	mmHg	0	0.0	0.0	-
b.	mmHg	20	19.9	0.1	0.007 bar
c.	mmHg	40	39.8	0.2	0.007 bar
d.	mmHg	80	79.8	0.2	0.007 bar
e.	mmHg	120	119.6	0.4	0.007 bar
f.	mmHg	230	229.5	0.5	0.007 bar
DESCENDING					
a.	mmHg	230	229.5	0.5	0.007 bar
b.	mmHg	120	119.6	0.4	0.007 bar
c.	mmHg	80	79.7	0.3	0.007 bar
d.	mmHg	40	39.9	0.1	0.007 bar
e.	mmHg	10	9.9	0.1	0.007 bar
f.	mmHg	0	0.0	0.0	0.007 bar

The values have been rounded off as per IS:2-1960(wherever applicable).
Pressure Conversion: -1 bar = -750.06 mmHg
Expended uncertainty reported is at approx 95% confidence level with K=2.
Average of Three Reading (Ascending & Descending). *Hysteresis:* 1.2 mmHg

6) Environmental Conditions : a) Temperature : 23±2°C b) Humidity : 50±10%

7) Calibration Status & Remark :
a. A Calibration Sticker has been affixed on EUC*.
b. Refer to report before use.

**********END OF THE CERTIFICATE**********

Calibrated by:	Approved by :
DANISH KHAN Calibration Engineer	SANJAY BAIS Quality Manager

ANNEXURE

WARM FOOT SOAK THERAPY – INTERVENTION PROTOCOL

Warm foot soak therapy is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days

Articles

A tray containing :

- Insulated foot bath bucket with warm water of temperature 37-40 degree Celsius : To soak feet
- Water boiling kettle : To boil water
- Water thermometer : To measure water temperature
- Two towel : To dry feet & cover the bucket/basin
- A digital sphygmomanometer : To assess the blood pressure
- Research instrument in the form of observation sheet

Preparation of environment :-

- Preparation of client :-
- provide patient a sitting position with dependent feet
- obtain consent from the patientexplain the procedure

Preparation of client :-

- provide patient a sitting position with dependent feet
- obtain consent from the patient
- explain the procedure

Steps of procedure

- Assess the pre interventional blood pressure (Blood pressure is taken 3 times within an interval of 5 minutes and calculated the mean) of patient in sitting position at left upper arm probably
- Carry the equipment and screen the patient if necessary
- If the feet look dirty ,wash first
- Fill the insulated foot bath bucket with warm water until it is half full then measure the temperature of water (37-40 degree Celsius) with a thermometer
- Dip & soak feet for 10-15 cm above ankle and then leave it for 15 minutes
- Cover the bucket with a towel to maintain the temperature
- When finished (after 15 min) ,lift the leg & dry it with a towel

After care of patient

- On completion of treatment remove and clean the equipment
- Leave the patient comfortable and chart the treatment
- Assessment of post interventional blood pressure

After care of articles

- Discard the water
- Do hand washing

ANNEXURE 8

PARTICIPANT INFORMATION SHEET-ENGLISH

Title of the study

"A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients"

Principal Investigator

Ms. Renjitha Ravi, M.Sc Cardiological /Cardiothorasic Vascular nursing student of Nursing College, AIIMS Bhopal

Guidance

Mrs. Ranjana Verma, Assistant professor, Nursing college, AIIMS Bhopal ,Dr.

Jisa George T, Assistant professor, AIIMS Bhopal (Co-Guide)

Dr. Ankur Joshi, Assistant professor, Dept. of CFM, AIIMS Bhopal (Co-Guide)

Introduction

I am conducting a study to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients. Hypertension is one of the most common worldwide disease afflicting humans. Therefore, health care professionals must not only identify & treat patients with hypertension but also promote a healthy lifestyle & preventive strategies to decrease the prevalence of hypertension in the general population. This study is to assess the effectiveness of warm foot soak therapy on the reduction of blood pressure among hypertensive patients attending NCD clinics of Berkheda Patani & Sai Baba Nagar.

Purpose of the study

This study is aimed to assess the effectiveness of warm foot soak therapy on the reduction of blood pressure among hypertensive patients attending NCD clinics of Berkheda Patani & Sai Baba Nagar.

a) Should I participate?

Participation in this research is completely voluntary.

b) What is expected of me if I join?

After screening the patient informed consent will be obtained from patient , there will be randomization of participants for experimental & control groups. Self structured questionaaire will be administered for collection of sociodemographic data & clinical data. Pre interventional blood pressure will be taken & intervention will be given to experimental groups along with their anti-hypertensive drugs (if prescribed by doctor) in stage 1& 2 hypertensive patients. Post interventional blood pressure assessment will be done as per intervention protocol.

c) How long will my participation in the study last?

The duration of the participation may last 3days (20 minutes/day) by the investigator.

d) Do I have to come separately for this study or will additional tests be necessary? No.

e) What are the potential benefits of joining?

There is no financial benefit involved in the study. Non pharmacological management techniques of hypertension include warm foot-soak therapy, which uses warm water to relax blood vessel muscle tissue and improve blood flow. Warm foot soak therapy are a straight forward, affordable, and effective therapy method that can be used to alleviate hypertension.

f) Potential loss and risk from participating in it?

There is no harm or risk due to participation in this study as per the evidence from previous studies, although minor risk like headache, dizziness, confusion & feeling of weakness can be there. There will be provision for hospital stay in case of any major adverse events as per the policy.

g) What will happen to the information collected about me?

All information collected will be kept strictly confidential

h) What happens if I change my mind about participating in this study?

You have the right to change your views at any time during the course of study without any damages or penalties.

6. Whom should I contact for more information regarding this or if I have any question/doubts in my mind later? If you want any information you can contact:

Dr. Shashank Purwar, Member Secretary, Institution Human Ethics Committee. Contact details: phone - 7773010099 and email -ihecpgr@aiimsbhopal.edu.in

Dr. Mamta Verma, Principal Nursing College, AIIMS Bhopal.

Contact details: phone- +919981540519, Email- principal.nursing@aiimsbhopal.edu.in

PARTICIPANT INFORMATION SHEET-HINDI

प्रतिभागी सूचना पत्र-अंग्रेजी

1.अध्ययन का शीर्षक: "उच्च रक्तचाप वाले रोतगयों में रक्तचाप को कम करने पर गमष पैर सोख तचतकत्सा की प्रभावशीलि का आकलन करने के तलए एक यादृच्छिक तनयंतत्रि परीक्षण"

2.प्रधान अन्वेर्क: सुश्री रंजीता र ि व , एम.एससी कातडषयोलॉतजकल / कातडषयोथोरे तसक वैस्कु लर नतसिंग छात्रा, नतसिंग कॉलेज, एम्स भोपाल

3.सलाह: श्रीमिी रंजना वमाष, सहायक प्राध्यापक, नतसिंग कॉलेज, एम्स भोपाल डॉ जीसा जॉजष टी, सहायक प्राध्यापक, एम्स भोपाल (सह-गाइड)

डॉ अंकु र जोशी, सहायक प्रोफे सर, सीएफएम तवभाग, एम्स भोपाल (सह-गाइड)

4.पररचय: मैं उच्च रक्तचाप से ग्रस्त रोतगयों के बीच रक्तचाप को कम करने पर गमष पैर सोखने की तचतकत्सा की प्रभावशीलि का आकलन करने के तलए एक अध्ययन कर रहा हं। उच्च रक्तचाप दु तनया भर में मनुष्ों को पीतिि सबसे आम बीमाररयों में से एक है। इसतलए, स्वास्थ्य देखभाल पेशेवरों को न के वल उच्च रक्तचाप वाले रोतगयों की पहचान और उपचार करना चातहए, बल्कि सामान्य आबादी में उच्च रक्तचाप के प्रसार को कम करने के तलए एक स्वस्थ जीवन शैली और तनवारक रणनीतियों को भी बढावा देना चातहए। यह अध्ययन रक्त की कमी पर गमष पैर सोख तचतकत्सा की प्रभावशीलि का आकलन करने के तलए है बेरख़ेि्ा पटानी और साईं बाबा नगर के एनसीडी क्लीतनकों में जाने वाले उच्च रक्तचाप के रोतगयों के बीच दबाव

5.इस अध्ययन का उद्दे श्य : इस अध्ययन का उद्दे श्य बेरख़ेि्ा पटानी और साईं बाबा नगर के एनसीडी क्लीतनकों में आने वाले उच्च रक्तचाप वाले रोतगयों के बीच रक्तचाप को कम करने पर गमष पैर सोखने की तचतकत्सा की प्रभावशीलि का आकलन करना है।

a.क्या मुझे भाग लेना चातहए? इस शोध में भागीदारी पूरी ि रह से स्वैच्छिक है।

b. अगर मैं शातमल हो जाऊं ि ो मुझसे क्या उम्मीद की जाि ी है? रोगी की स्क्रीतनंग के बाद रोगी से सूतचि सहमति प्राप्त की जाएगी, प्रायोतगक और तनयंत्रण समूहों के तलए प्रतिभातगयों का यादृच्छिकीकरण तकया जाएगा। सामातजक-जनसांच्छिकीय डेटा और नैदातनक डेटा के संग्रह के तलए स्व-संरतचि प्रश्नावली का संचालन तकया जाएगा। स्टेज 1 और 2 हाइपरटेंतसव रोतगयों में प्री-इंटरवेंशनल ब्लड प्रेशर तलया जाएगा और प्रयोगात्मक समूहों को उनकी ए टी-हाइपरटेंतसव दवाओं (यतद डॉक्टर द्वारा तनधाषररि तकया गया है) के साथ हस्तक्षेप तदया जाएगा। पोस्ट इंटरवेंशनल ब्लड प्रेशर का मूल्ांकन इंटरवेंशन प्रोटोकॉल के अनुसार तकया जाएगा।

c.अध्ययन में मेरी भागीदारी कब ि क चलेगी? अन्वेर्क द्वारा भागीदारी की अवतध 3 तदन (20 तमनट/तदन) ि क हो सकि ी है।

d.क्या मुझे इस अध्ययन के तलए अलग से आना होगा या अतिररक्त परीक्षण आवश्यक होगे? नही।

e.शातमल होने के संभातवि लाभ क्या ह? अध्ययन में कोई तवत्तीय लाभ शातमल नही ं है। उच्च रक्तचाप की गैर और्धीय प्रबंधन ि कनीकों में वामष फु ट-सोक थेरे पी शातमल है, जो रक्त वातहका की मांसपेतशयों के ऊिकों को आराम देने और रक्त प्रवाह में सुधार करने के तलए गमष पानी का उपयोग करि ी है। वामष फु ट सोक थेरे पी एक सीधी, सस्ती और प्रभावी तचतकत्सा पद्धति है तजसका उपयोग उच्च रक्तचाप को कम करने के तलए तकया जा सकि ा है।

f. इसमें भाग लेने से संभातवि नुकसान और जोच्छखम। तपछले अध्ययनों के साक्ष्य के अनुसार इस अध्ययन में भाग लेने से कोई नुकसान या जोच्छखम नही ं है, हालांतक तसरददष, चक्कर आना, भ्रम और कमजोरी की भावना जैसे मामूली जोच्छखम हो सकि हैं। पॉतलसी के अनुसार तकसी भी ब्रि प्रतिकू ल घटना के मामले में अस्पिाल में रहने का प्रावधान होगा।

g. मेरे बारे में एकत्र की गई जानकारी का क्या होगा? एकत्र की गई सभी सूचनाओं को क़िाई से गोपनीय रखा जाएगा

h.यतद मैं इस अध्ययन में भाग लेने के बारे में अपना तवचार बदल द्व ं ि ो क्या होगा? आपको अध्ययन के दौरान तकसी भी समय तबना तकसी नुकसान या दंड के अपने तवचार बदलने का अतधकार है।

6.इस बारे में अतधक जानकारी के तलए मुझे तकससे संपकष करना चातहए या यतद बाद में मेरे मन में कोई प्रश्न/शंका हो ि ो? यतद आप कोई जानकारी चाहि हैं ि ो आप संपकष कर सकि हैं:

डॉ. शशांक पुरवार, सदस्य सतचव, संस्था मानव आचार सतमति। संपकष तववरण: फोन - 7773010099 और ईमेल -ihecpgr@aiimsbhopal.edu.in

डॉ. ममिा वमाष, तप्रंतसपल नतसिंग कॉलेज, एम्स भोपाल। संपकष तववरण: फोन- +919981540519, ईमेल- तप्रंतसपल.नतसिंग@aiimsbhopal.edu.in

ANNEXURE 8

PARTICIPANT INFORMED CONSENT FORM

प्रतिभागी सूचना सहमति प्रपत्र

[PARTICIPANT INFORMED CONSENT FORM (PICF)]

इस अध्ययन के तिए प्रतिभागी का पहचान नंबरः .....

Participant Identification Number for this Study: .....

अनुसंधान का शीर्षकः : "उच्च रक्तचाप वाले रोगियों में रक्तचाप को कम करने पर िमम पैर सोख गचककत्सा की प्रभावशीलता का आकलन करने के गलए एक यादगृ छिक गनयगं ित परीक्षण"

Title of Project: A randomized controlled trial to assess the effectiveness of warm foot soak therapy on reduction of blood pressure among hypertensive patients

शोधतकार् छात्र का नाम : सुश्री रंजीताा रिव , फोन नं: 7025084292

Name of Student Investigator: Ms. Renjitha Ravi, Tel No.(s): 7025084292

मागर्दशर्क (गाइड) : रंजना वमार्, सहायक प्रोफे सर, नितसंग कॉताे ज, एम्स भोपाता सह मागर्दशर्क/कों : डॉ जीसा जॉजर् टी, सहायक प्रोफे सर, नितसंग कॉताे ज, एम्स भोपाता डॉ अंकु र जोशी ,सहायक प्रोफे सर, एम्स भोपाता

Name of Thesis Guide: : Mrs. Ranjana Verma, Assistant Professor, Nursing College, AIIMS Bhopal (Guide) Dr. Jisa George T, Assistant Professor, Nursing College, AIIMS Bhopal (Co-Guide) Dr. Ankur Joshi, Assistant professor (CFM) AIIMS Bhopal (Co-Guide)

मैंने िदनांक ..... के सूचना पत्रक संस्करण ।। में िदए गए सभी ताथ्ाोंाें को सावधानीपूवर्क पढ तिया है/ मुझे अपनी भार् ाां में स्पष्ट रूप से िवस्तारपूवर्क समझा िदया गया है, और मैंने ताथ्ाोंाें को पूणतर्ः समझ तिया है। मैं पुिष्ट कररा/ कररी हूँ, िक मुझे सवाता पूछने के अवसर प्रदान िकए गए।

The contents of the information sheet version II dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृ ति एवं उद्दे श्य और इसके संभाितव जोखखमों / ताभाों ताथा अध्ययन की अनुमाितन अविध एवं अन्य प्रासंिगक जानकारी के बारे में िवस्तारपूवर्क समझा िदया गया है। मुझे तपा है िक इस अध्ययन में मेरी भागीदारी स्वैच्छखक है ताथा मैं इस अध्ययन से िकसी भी समय िबना कोई कारण तबाए, अपना नाम वापस ताे ने के तिए च्छस्वंत्र हं और नाम वापस ताे ने पर मेरी िचिकत्सा देखभाता या कानूनी अिधकारों पर कोई प्रभाव नही ं पडेगा।

The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

मैं समतझा/समतझी हं िक इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे िचिकत्सीय दस्तावेजों के िकसी भी भाग को एम्स के िजम्मेदार व्यखक्तयों द्वारा ही देखा जाएगा। मैं इन व्यखक्तयों को मेरे ररकॉडर् प्राप्त करने की अनुमति प्रदान कररा/ कररी हूँ।

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for this individual to have access to my records

मैं उक्त अध्ययन में भाग ताा े ने के तिए सहतम हं/**I agree to take part in the above study.**

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का िनशान) **(Signature/Left Thumb Impression)**

िदनांक/**Date**..... स्थान/**Place** .....

प्रतिभागी का नाम/**Name of the participant**.....

ितपा/पति/पत्नी का नाम /**Son/Daughter/Spouse of**.....

डाक का पूरा तपा /**Complete Postal Address** .....

अगर अिशितक्ष हों / **If illiterate.**

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है और प्रश्न पूछने का अवसर िदया गया है। मैं पुिष्ट करता हं िक व्यखक्त ने छस्वंत्र रूप से अपनी सहमति दी है

The information sheet has been read and explained to the participant and given the opportunity to ask questions. I confirm that the individual has given consent freely.

िदनांक/**Date** :

तएएआर या िनष्पक्ष गवाह का नाम / **Name of LAR or impartial witness :**

तपा / **Address :**

प्रमाितण िकया जाताा है िक उक्त सहमति मेरी उपखस्थति में प्राप्त की गई

_____

छात्र शोधतकार् के हस्ताक्षर िदनांक..... स्थान.....

Signature of the student Investigator Date ..... **Place** .....

Start | Enter | Results | Examples | Help

Sample Size For Comparing Two Means

Input Data

Confidence Interval (2-sided)	95%
Power	80%
Ratio of sample size (Group 2/Group 1)	1

	Group 1	Group 2	Difference*
Mean	1.243	0.641	0.602
Standard deviation	0.622	0.594	
Variance	0.386884	0.352836	

Sample size of Group 1	17
Sample size of Group 2	17
Total sample size	34

*Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

ANNEXURE

MASTER DATA SHEET KEY

Abbreviation	Full form	Coding
PIN	Participant Identification Number	1- 60
AGE	Age Of Participant	1 : <30 years 2 : 30-60 years 3 : > 60 years
GENDER	Gender of participant	1 : Male 2 : Female
OCCUPATION	Occupation of participants	1 : Govt employee 2 : Private employee 3 : Home maker 4 : others
DIET	Dietary pattern of Participants	1 : Vegetarian 2 : Non vegetarian
SMOKING	Smoking Habit of participants	1 : Smoker 2 : Non-smoker
ALCOHOLISM	History of Alcoholism among participants	1 : Yes 2 : No
BMI	Body Mass Index	1 : <18.5 Kg/ m2 2 : 18.6-24.9 Kg/ m2 3 : 25 Kg/ m2
DOH	Duration of hypertension	1 : < 1 year 2 : 2-4 years 3 : 4 years
UAHD	Use of Anti-Hypertensive Drug	1 : Yes 2 : No
NOAHD	No. of Anti-Hypertensive Drug	1 : 1 2 : 2 3 : >2 4 : No Medicine
POC	Presence Of Co-morbidity	1 : Yes 2 : No
TOCP	Type Of Co-morbidity	1 : DM 2 : No 3 : Others

MASTER SHEET OF MAIN DATA COLLECTION

PART 1 & 2

PIN	AGE	GENDER	OCCUPATION	DIET	SMOKING	ALCOHOLISM	BMI	DOH	UOAHD	NOAHDU	POC	TOCP
1	3	2	3	1	2	2	2	2	1	2	1	1
2	3	2	3	1	2	2	2	2	1	1	1	1
3	2	2	3	1	2	2	2	3	1	1	1	1
4	3	2	3	1	2	2	3	3	1	1	1	1
5	2	2	3	1	2	2	3	3	1	1	1	1
6	2	2	3	1	2	2	3	2	1	1	2	2
7	2	2	3	1	2	2	1	2	1	1	1	1
8	3	2	3	1	2	2	3	1	1	1	1	1
9	2	1	2	2	2	2	3	1	1	1	2	2
10	2	2	3	1	2	2	3	2	1	1	1	1
11	2	1	4	2	1	1	3	3	1	1	2	2
12	2	2	3	1	2	2	3	2	1	1	1	1
13	2	1	4	1	2	2	3	3	1	1	1	1
14	3	1	4	1	2	2	2	3	1	1	1	1
15	2	1	4	1	2	2	3	2	1	1	1	1
16	3	1	4	1	2	2	3	2	1	1	1	1
17	2	2	3	2	2	2	2	2	1	1	1	1
18	2	1	2	1	2	2	3	2	1	2	1	1
19	2	2	3	1	2	2	3	3	1	2	1	1
20	3	2	3	1	2	2	2	3	1	1	1	1
21	2	1	4	1	1	1	3	3	1	1	1	1
22	3	2	3	1	2	2	3	3	1	1	1	1
23	3	1	4	1	2	2	3	2	1	1	1	1
24	3	2	3	1	2	2	2	3	1	1	1	1
25	3	1	4	2	1	2	3	3	1	1	1	1
26	3	2	3	2	2	2	2	3	1	1	1	1
27	2	1	2	1	2	2	3	2	1	1	1	1
28	2	1	4	1	2	2	3	3	1	1	1	1
29	2	1	3	1	2	2	2	2	1	1	1	1
30	2	1	4	2	2	2	3	2	1	1	2	2
31	2	1	4	2	2	2	3	2	1	1	2	2
32	2	2	3	1	2	2	3	1	1	1	1	1

33	2	2	4	2	2	2	2	2	4	2	1	1
34	2	1	3	1	2	2	2	2	1	1	1	1
35	2	2	3	1	2	2	2	2	1	1	1	1
36	2	2	3	1	2	2	2	2	1	1	2	2
37	2	2	3	1	2	2	2	1	1	1	2	2
38	2	2	3	1	2	2	3	1	1	1	2	2
39	2	1	2	2	1	1	2	2	1	1	1	1
40	2	2	3	1	2	2	3	3	1	1	1	1
41	2	2	3	2	2	2	3	1	1	1	1	1
42	2	2	3	2	2	2	3	2	1	1	1	1
43	2	2	3	1	2	2	2	2	1	1	1	1
44	2	1	2	2	2	2	2	2	1	1	1	1
45	2	1	2	2	2	2	3	3	1	1	2	2
46	2	1	4	2	2	2	3	3	1	1	1	1
47	2	1	2	2	2	2	2	1	1	1	2	2
48	2	1	2	1	2	2	2	2	1	1	2	2
49	2	1	4	2	2	2	2	3	1	1	1	1
50	2	2	3	1	2	2	2	1	1	1	2	2
51	2	2	3	1	2	2	2	1	1	1	2	2
52	2	1	4	2	2	2	3	1	1	1	1	1
53	2	2	3	2	2	2	2	1	1	1	1	1
54	2	1	2	2	2	1	2	1	1	1	1	1
55	3	1	4	1	2	2	2	3	1	1	1	1
56	2	2	3	1	2	2	2	3	1	1	2	2
57	2	2	3	2	2	2	3	2	1	1	1	1
58	2	2	3	1	2	2	3	3	1	1	1	1
59	2	1	4	2	2	2	3	3	1	1	2	2
60	2	1	4	1	2	2	3	3	1	1	1	1

APPENDIX 12

RANDOMIZATION PLAN USED FOR FINAL STUDY

A Randomization Plan from http://www.randomization.com

1. No intervention :
2. warm foot soak therapy :
3. No intervention :
4. No intervention :
5. warm foot soak therapy :
6. warm foot soak therapy :
7. No intervention :
8. No intervention :
9. No intervention :
10. warm foot soak therapy :
11. warm foot soak therapy :
12. warm foot soak therapy :
13. warm foot soak therapy :
14. warm foot soak therapy :
15. warm foot soak therapy :
16. No intervention :
17. No intervention :
18. Warm foot soak therapy :
19. No intervention :
20. warm foot soak therapy :

21. warm foot soak therapy : .....

22. No intervention : .....

23. No intervention : .....

24. warm foot soak therapy : .....

25. warm foot soak therapy : .....

26. No intervention : .....

27. No intervention : .....

28. warm foot soak therapy : .....

29. No intervention : .....

30. warm foot soak therapy : .....

31. No intervention : .....

32. No intervention : .....

33. warm foot soak therapy : .....

34. No intervention : .....

35. No intervention : .....

36. Warm foot soak therapy : .....

37. No intervention : .....

38. Warm foot soak therapy : .....

39. No intervention : .....

40. Warm foot soak therapy : .....

41. No intervention : .....

42. No intervention : .....

43. Warm foot soak therapy : .....

44. No intervention : .....

45. No intervention : .....

46. Warm foot soak therapy : .....

47. Warm foot soak therapy : .....

48. Warm foot soak therapy : .....

49. Warm foot soak therapy : .....

50. Warm foot soak therapy : .....

51. No intervention : .....

52. Warm foot soak therapy : .....

53. No intervention : .....

54. Warm foot soak therapy : .....

55. No intervention : .....

56. Warm foot soak therapy : .....

57. Warm foot soak therapy : .....

58. No intervention : .....

59. No intervention : .....

60. No intervention : .....

60 subjects randomized into blocks of 30 30 To reproduce this plan, use the seed 28190 along with the number of subjects per block/number of blocks and (case-sensitive) treatment labels as entered originally. Randomization plan created on 20/09/2023, 5: 17: 58 PM